7312 U-007-307.48

US DOE, SUPPLEMENTAL GUIDANCE TO RISK ASSESSMENT WORK PLAN ADDENDUM, PREPARED FOR REMEDIAL INVESTIGATION AND FEASIBILITY STUDY, FERNALD ENVIRONMENTAL MANAGEMENT PROJECT - (USED AS A REFERENCE IN OU5 RI APP. A AND OU 5 FS APP. H)

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

BOOK NO. 1 OF 1

000001

SUPPLEMENTAL GUIDANCE

TO THE

RISK ASSESSMENT

WORK PLAN ADDENDUM
JUNE 1992

FERNALD ENVIRONMENTAL
MANAGEMENT PROJECT

FERNALD, OHIO

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

BOOK 1 OF 1

CONTROL NUMBER

0028

000002

F- 7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

INDEX TO THE SUPPLEMENTAL GUIDANCE

August 19, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

Title: Index to Supplemental Guidance	[- 7312
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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
03/31/94	0	Provides an index to the Supplemental Guidance and will be updated as supplements are added/changed
05/04/94	1	Reflect removal of 94-013, Beryllium Guidance
08/19/94	2	Reflect revision of 94-013, Beryllium Guidance; addition of 94-014, Speciation of Total Chromium in Surface Soil; addition of 94-015, Soil Ingestion Rates for the RME and CT Farmer; and 94-016, Significant Figures Guidance for Risk Calculations.

No.	Title	Explanation
RASOP: 94-1	Performing QA/QC Checks on Risk Assessment Calculations	Provides guidelines for performing Quality Assurance/Quality Control checks on risk assessment calculations for Remedial Investigation/Feasibility Study reports at the Fernald Environmental Management Project
94-001	Ecological Risks for Operable Units 1 through 4	Supplements Section 5.1.5 (page 5-20) by providing guidance on how ecological risk will be addressed by Operable Units 1 through 4
94-002	Guidelines for Determining Contaminants of Potential Concern	Primarily supplements Section 4.0, specifically Section 4.2 (page 4-2), by providing requirements for determining contaminants of potential concern and adding a screening procedure for contaminants of concern
94-003	Ingestion of Homegrown Fruits and Vegetables	Supplements Section 7.2.1.4 (page 7-9) by describing the rationale for quantity ingestion of fruits and vegetables
94-004	Population Distribution	Supplements Section 5.1.4 (page 5-11) by describing population distributions
94-005	Use of Data with MDS/SQL and CRDL/CRQL	Supplements Section 4.2.2 (page 4-3) by providing guidance for use of data when both MDS/SQLs and CRDL/CRQLs are used
94-006	Exposure Scenarios, Receptors, and Input Parameters	Supplements Sections 5.1.4.2 and 5.1.4.3 (pages 5-14 through 5-17) to reflect changes to input parameters
94-007	Central Tendency Analysis	Supplements Section 7.2.2.1 (page 7-16) by providing guidance on the preparation of central tendency analysis
94-008	Receptor Guidance	Supplements Sections 5.1.4.2 and 5.1.4.3 (pages 5-14 through 5-17) by listing exposure scenarios and pathways
94-009	PRG/PRL Development	Supplements Section 10.1.2 (page 10-4 through 10-12) by providing requirements for the methods to be used for developing preliminary remediation goals and proposed remedial levels

No.	Title	Explanation
94-010	Children's Inhalation Rates	Supplements Section 7.2.2.1 (page 7-16) by providing a calculated value for the child's inhalation rate
94-011	Dermal Slope Factors for PAHs (or other COCs)	Supplements Section 8.2 (page 8-2) by providing guidance to seek out dermal factors when information is unavailable in IRIS, HEAST, or ECAO documentation
94-012	Human Surface Area Dermal Contact with Soils	Supplements Section 7.2.2.1 (page 7-16) by providing the physiological parameter to be used for the human body surface area during calulation of dermal exposure
94-013	Beryllium Guidance	Provides the guidance for calculating PRGs and performing dermal risk assessment for beryllium based on negotiations with the U.S. Environmental Protection Agency.
94-014	Speciation of Total Chromium in Surface Soil	Provides guidance for establishing the speciation of chromium in surface soils at the Fernald Environmental Management Project (FEMP).
94-015	Soil Ingestion Rates for the RME and CT Farmer	Text and documentation to be used for the soil ingestion rates for the RME and CT farmer.
94-016	Significant Figures Guidance for Risk Calculations	Defines the required number of significant figures agreed upon by the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) for presenting risk calculations in remedial investigation/feasibility study (RI/FS) and CRARE reports submitted to the regulatory agencies.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

ECOLOGICAL RISK EVALUATION FOR OPERABLE UNITS 1 THROUGH 4

SUPPLEMENT NO. 94-001
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

Title: Ecological Risk Evaluation for Operable Units 1 through 4	73 12
SUPPLEMENT NO. 94-001 REVISION NO. 1	
Effective Date: March 31, 1994	Page 1 of 4

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
08/05/93	0	Provides guidance on how ecological risks will be addressed by Operable Units 1 through 4
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

1.0 OBJECTIVE

Ecological risk assessment must be considered as part of the Remedial Investigation (RI)/Feasibility Study (FS) process pursuant to Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) guidance. The Fernald Environmental Management Project (FEMP) has been divided into five operable units. The RI/FS process will be conducted for each of the five operable units. Operable Unit 5 has the responsibility to remediate the flora, fauna, surface water and the majority of soil at the FEMP. Therefore, it was negotiated between the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) that the Operable Unit 5 RI would consider site-wide ecological risk in the baseline risk assessment. This is documented in the Amended Consent Agreement between the DOE and EPA (September 1991). Any areas that were identified as posing a potentially significant ecological risk in the Operable Unit 5 RI will be evaluated in the Operable Unit 5 FS.

The overall strategy for addressing ecological risk issues in the Operable Unit 5 baseline risk assessment has been formulated and discussed with the EPA's Biological Technical Assistance Group (BTAG) in a meeting on February 17, 1993. It was determined that one of the primary purposes of the ecological risk assessment is to identify areas that may need to be remediated from an ecological standpoint that would not be remediated from a human health standpoint. The strategy developed by Operable Unit 5 screens out areas of Operable Units 1 through 4 which would be remediated from consideration in the ecological risk assessment based on the assumptions that 1) Operable Units 1 through 4 will be fully remediated to human health standards and 2) minimal habitat exists in Operable Units 1 through 4.

2.0 SUPPLEMENTAL GUIDANCE

For their RI reports, Operable Units 1 through 4 will note that the Site-wide Ecological Risk Assessment is being prepared by Operable Unit 5 according to CERCLA guidance and the understanding reached with the EPA Region V/BTAG representative at the February 17, 1993 meeting and formalized with their acceptance of the FEMP Site Strategy for Assessing Ecological Risks; that is, Operable Units 1 through 4 will not contain a baseline ecological risk assessment in their RI reports. The baseline ecological risk data from the Site-Wide Characterization Report will be referenced. Operable Unit 5 will prepare, as part of its RI report, a Site-wide Ecological Risk Assessment which will evaluate potential risks from current concentrations of site contaminants to ecological receptors inhabiting on-site and off-site areas not presently targeted for remediation based upon human health concerns. This approach will fulfill the requirements of the Amended Consent Agreement and CERCLA pertaining to the completion of the Site-wide Ecological Risk Assessment.

For their FS reports, Operable Units 1 through 4 will derive and tabulate preliminary remediation goals based upon risk, applicable or relevant and appropriate requirements, and health-based or other technical considerations. One of the technical considerations in preliminary remediation goal (PRG) development for the respective operable unit's contaminants of concern will be the benchmark criteria developed for the screening document and the Site-wide Ecological Risk Assessment. The tabulation of PRGs will be carried through the FS to the detailed analysis of alternatives. As part of the detailed analysis, a qualititative evaluation will be presented of the potential ecological risk for each alternative that leaves residual contaminant levels

in place that exceed benchmark criteria. In addition, a discussion of ecological risk assessment will be incorporated into the cumulative impact analysis.

3.0 SUPPORTING INFORMATION

Limiting the scope of the ecological risk assessment to the area of Operable Unit 5 raises several questions aand further justifies the need to evaluate ecological risks qualitatively for Operable Units 1 thru 4. First, statements in RI/FS documents for Operable Units 1 through 4 that defer evaluation of operable unit-specific ecological risks to the Operable Unit 5 RI are inappropriate because baseline ecological risk assessments for Operable Units 1 through 4 will not be conducted by Operable Unit 5. Second, only those contaminants present in detectable quantities in the physical area of Operable Unit 5 and recorded in the RI/FS database will be evaluated in the Site-wide Ecological Risk Assessment. It is possible that some contaminants not present in Operable Unit 5 in detectable concentrations will be found in detectable concentrations in Operable Units 1 through 4. Third, because only contaminants considered to pose risks to human health will be evaluated in Operable Units 1 through 4, it is possible that other contaminants may be present that represent risks to ecological receptors but not to humans. Without an operable unit-specific ecological baseline risk assessment, these contaminants would not be identified.

The FEMP expects that reducing contaminant levels in Operable Units 1 through 4 to concentrations low enough to protect human health will protect ecological receptors as well. Any contaminants identified in Operable Units 1 through 4 that may impact ecological receptors and which were not evaluated in the screening document will be evaluated by developing appropriate criteria in a manner consistent with the methods used to establish benchmark criteria in the screening document. The FEMP understands that this approach is contingent upon EPA's acceptance of the Screening Level Ecological Risk Assessment, which was submitted in August 1993.

The Comprehensive Response Action Risk Evaluation (CRARE) reports will examine only potential cumulative human health risks for the operable units and will not focus on risks to ecological receptors.

When implementing this strategy, the evaluation of ecological risks should be kept in perspective because of the substantial remedial activities planned at the FEMP to protect human health. The areas of Operable Units 1 through 4 will be extensively remediated based on stringent human health criteria, while Operable Unit 5 will be completing the Site-wide Ecological Risk Assessment to evaluate risk to ecological receptors in the remaining areas of the FEMP (note: more than 80 percent of the FEMP is in Operable Unit 5). Furthermore, detailed site surveys have not shown obvious stress to ecological receptors. As a consequence, qualitative discussions on ecological risk should more than suffice for the FS reports for Operable Units 1 through 4.

4.0 REFERENCES

Saric, J.A., U.S. Environmental Protection Agency, October 1993, letter to J.R. Craig, United States Department of Energy, Fernald Environmental Management Project, Subject: Ecological Risk Assessment Strategy.

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

GUIDELINES FOR DETERMINING CONTAMINANTS OF POTENTIAL CONCERN

SUPPLEMENT NO. 94-002
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

Title: Guidelines for Determining Contaminants of Potential Concern	- 7312
SUPPLEMENT NO. 94-002 REVISION NO. 1	
Effective Date: March 31, 1994	Page 1 of 8

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DATE	REV. NO	DESCRIPTION
08/26/93	0	Provides the requirements for determining contaminants of potential concern, which must be used for all FEMP risk assessments
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

1.0 **OBJECTIVE**

The following process was developed in consultation with U.S. Environmental Protection Agency (EPA) and will be used to determine contaminants of potential concern for the FEMP, consistent with EPA direction.

2.0 **SUPPLEMENTAL GUIDANCE**

The following terms will be used in all risk assessments conducted at the FEMP:

- **Constituents of Potential Concern (COPCs)** - all constituents which are determined or assumed to be above background following statistical analysis of the data.
- **Contaminants of Potential Concern (CPCs)** - all contaminants which remain a concern after the toxicological pre-screening procedure has been applied to the COPCs.
- **Contaminants of Concern (COCs)** - all contaminants which remain a concern after fate and transport evaluation, exposure point calculations, risk calculations, and post screening evaluation has been done on CPCs (i.e., at the end of the baseline risk evaluation process).

The process of determining COCs involves statistical screening, pre-screening, and post-screening procedures as defined below.

3.0 **SUPPORTING INFORMATION**

3.1 Statistical Analysis Procedure for Determining COPCs

Statistical comparison of data collected on site (soils, sediment, sludge, surface water, perched groundwater and groundwater data down-gradient of the site) versus background data will be accomplished as follows:

3.1.1 Determination of the proper statistical analytical procedure is dependent on the data sets being analyzed. The method of choosing the statistical analysis to determine COPCs is shown in Figure 1. Procedures which will be used include:

3.1.1.1 t-Tests (ANOVA for multiple comparisons) on log-transformed data - If the data sets can be shown to be lognormally distributed (which is often the case with environmental analyte concentration data), the proportion of non-detects is not excessive and the log-variances are similar, the data will be log-transformed and t-Tests will be run to compare site data to background data. The accuracy of the results depends on the level of adherence to the assumptions of log-normality of the data. Probability plots and non-parametric tests such as the Kolmogorov-Smirnov test or the Shapiro-Wilk test (Shapiro-Francia test for data sets with n>50) will be used to assess the normality of the log-transformed data. Bartlett's test for equality of variances will be used to assess comparability of log-variances.

For non-detects, the simple substitution method (1/2 SQL) will be used in the calculation.

If the probability level of the t-Test (or the ANOVA) is statistically significant (at

approximately the 95 percent confidence level) then we conclude that there is sufficient evidence to indicate that the site constituent concentrations are different from background; therefore, the constituent will be considered a CPC.

3.1.1.2 t-Tests (ANOVA for multiple comparisons) on untransformed data - Standard t-Test (ANOVAs) procedures will be employed if the data can not be shown to be lognormally distributed but can be identified as normally distributed and the variances (site and background) are not statistically significantly different from each other. Estimates or estimates using simple substitution will be used under the same conditions as above except that the data will not be transformed.

3.1.1.3 Parameter estimation techniques based on other distribution (e.g., Weibull, F, exponential, etc.) may be used if there is strong statistical and literature evidence that these distributions better describe the data. Although these distributions are not typical for environmental data, sometimes radionuclide data follows one of these distributions.

3.1.1.4 Non-parametric ANOVA (Kruskal-Wallis or Mann-Whitney U) - non-parametric procedures will be used if the data are significantly divergent from the normal or lognormal distributions. (With these non-parametric ANOVA procedures, the data values are replaced by their relative ranks. Although there is some loss of statistical power, this protects against deviations from normality which would make the results of a t-Test or parametric ANOVA invalid.) The Kruskal-Wallis is used with multi-category data (e.g. multiple groundwater wells with multiple rounds of data) and the Mann-Whitney U is used for two-category data. (The Mann-Whitney U test and the Wilcoxon Rank Sum are directly related and are equivalent for all practical purposes.)

3.1.1.5 The distribution of the data from small data sets can not be adequately assessed. Different procedures need to be employed to determine if the constituent should be treated as a CPC.

If there are fewer than five samples and the constituent was detected at least once, a comparison of the maximum detected value to the background 95th percentile will be performed as in Section 3.1.2. In cases where the constituent was not detected, process knowledge and professional judgment will be employed to determine if it is probable that the constituent should be present even though it was not detected. Please see Section II for discussion.

If a constituent was detected fewer than seven times but at least four times, the CPC determination technique outlined in Section 3.1.1.4 will be used.

3.1.1.6 Other techniques - Where there are greater than 50 percent non-detects, other techniques must be employed to determine if a constituent should be considered a CPC. With high proportions of non-detects, the procedure(s) become simply a comparison of the distribution of detection limits NOT of the distributions of the concentration data. One non-parametric procedure that can be used is the Test for Proportions. This test compares the proportion of non-detects between two populations. This procedure categorizes all results into two categories, detect or non-detect. Obviously, this is a drastic analytical technique. But, in a high proportion of non-

detects, statistical procedures often yield practically meaningless results. Good scientific and statistical judgement should be used to judge the validity of any result.

3.1.2 An additional statistical procedure that will be used to screen for CPCs is the comparison of individual data points to the 95th percentile (calculated based on the appropriate distribution) of the uncontaminated background data for each constituent not already identified as a CPC. This technique will be used to protect against "hot spots" being "averaged out". If any site constituent concentration exceeds the calculated 95th percentile, then this constituent is added to the CPC list. This procedure will be used only to include the CPC list constituents not identified previously. It will not be used to remove a constituent from the CPC list.

3.1.3 Other data set comparison considerations:

3.1.3.1 For meaningful results, the science of statistical analysis relies on the adherence to the assumptions of the statistical procedure being employed. Numbers can be run through almost any statistical procedure, but if the assumptions of the procedure are not met, the analysis results are meaningless.

3.1.3.2 Parametric procedures should be used when possible. Parametric procedures, such as those based on the Guassian (normal) distribution, are more statistically powerful then non-parametric procedures since information about the distribution is known beforehand. Most non-parametric procedures rely on ranks or counts of data and not the observed values as do parametric procedures. Usually, moderate deviations from Normality can be tolerated by most parametric procedures.

3.1.3.3 Non-parametric procedures such as Kruskal-Wallis, Mann-Whitney, or Wilcoxon Signed Rank substitute ranks for observed values. This fact allows for "distribution-free" analysis, but the loss of information reduces the reliability of the results. Generally, non-parametric procedures require larger sample sizes than do parametric procedures to attain the same accuracy level. This should not preclude their use. However, non-parametric procedures yield more reliable results than do parametric procedures on data that violate the assumptions of normality.

3.1.3.4 Interpretation of statistical results can often be misleading to the non-statistician. The interpretation of a single statistical test (assuming all of the proper assumptions have been met) may be straightforward. However, there are many factors that make interpretation anything but trivial. Some major problems to statistical analysis and interpretation are:

a. High proportion of non-detects.
b. Non-symmetrically disturbed data.
c. Apparent bimodal (or polymodal) data - often indicating that the data were probably collected from different populations.
d. Highly spatially correlated data (non-random distribution of data).
e. Large differences in variability between site and background data.
f. Individually, statistical procedures may fail to detect significant differences, but a combined analysis of all constituents may yield highly

significant results. For example, there are ten potential CPCs. All ten potential CPCs demonstrate site mean concentrations greater, BUT not significantly greater (at the 95% level), than background. If there were no differences between site and background, we would expect about an even split between which mean concentration were higher (site or background). Assuming that the populations of site and background were the same (no contamination), the chance of the means of all ten samples being greater than the background means is approximately 1 to 1,000. Clearly, there is evidence here to warrant additional analyses.

3.2. Toxicological Screening Procedure for Determining CPCs and COCs

3.2.1. Screening Procedure (post-statistical analysis).

3.2.1.1. Class A/B carcinogens are to be included as COC's unless specific directions apply for removal. For others, evaluate contaminant concentrations, frequency of detection, persistence, and distribution among media.

3.2.1.2. If a contaminant is identified in only one sample and in only one medium or is unvalidated, was not found in other media, or was not identified as a process source contaminant, consider removal. Removal shall not take place without an additional toxicological review.

3.2.1.3 Remove those chemicals that are known laboratory contaminants and have concentrations of less than ten times the highest blank concentration (e.g., Acetone, 2-Butanone, Methyl-ethyl-ketone, Methylene Chloride, Phthalate Esters, etc.).

3.2.1.4. Essential micro-nutrients whose concentrations are within 10 percent above background and known to be non-toxic (e.g., Na, K, Mg, Ca, Fe, etc.) can be deleted.

3.2.1.5. Identify and remove classes of chemical compounds that are non-specific (e.g., total organic carbon (TOC), total organic nitrogen (TON), chlorinated hydrocarbons, etc.).

3.2.1.6. Identify compounds known to be derived from off-site sources (e.g., autos, off-site factory discharges, etc.). Consider removal if no possible contribution to site risk is identified. Explain.

3.2.1.7. Identify and remove compounds that are ubiquitous in nature and considered to be non-toxic (e.g., Al, Si, Cl). Consider multiple media, pathways, and target organs of simultaneous exposure.

3.2.1.8. Compounds with low potential for toxicity (greater than 5.0 gms/kg, body weight) and whose concentrations are less than 1.0 ppm can be removed.

3.2.1.9. As a secondary screen and to assure consistency, compare remaining

contaminants and their concentrations and the chemicals that were removed with back-calculated risk-based concentration of screening from RAGS Part B.

3.2.1.10. Review the list of chemicals removed and identify those whose toxic effects may be exerted upon a common target organ. Examine toxicity, concentrations, and additive/synergistic effects due to concomitant exposure. Consider structure-activity relationships or other chemical similarities. Discuss over/under estimation of risk due to grouping.

3.2.1.11. For general guidance, use the philosophy that we must include the contaminants that provide risk to potential receptors. If removal is justified, describe the rationale and/or if professional judgement supports removal of contaminants.

3.2.2 Post Screening Procedure

3.2.2.1 If quantitative assessment of a contaminant results in a cancer risk of less than $10E^{-7}$, or has a hazard index (HI) of less than 0.1, consider removal.

3.2.2.2 Using the Concentration-Toxicity screen, calculate the chemical scores and relative risk. Identify those contaminants, on a percentage basis, in a particular medium that will most likely contribute the major risk for that scenario.

a. Chemical contaminants whose relative contribution to the total risk from a medium is less than 1 percent (RAGS) may be eliminated. After removal however, you should:

1. Re-examine the chemicals discarded. Is a particular target organ impacted by those chemicals? Consider possible additive or synergistic effects.

2. If a particular target organ is affected by such chemicals, total the relative percentage contributions for each of the chemicals or congeners. If the total risk of all equals or exceeds 5 percent of the total risk, re-enter those chemicals and identify the reason for their in conclusion.

4.0 **REFERENCES**

None.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

INGESTION OF HOMEGROWN FRUITS AND VEGETABLES

SUPPLEMENT NO. 94-003
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000021

Title: Ingestion of Homegrown Fruits and Vegetables	7312
SUPPLEMENT NO. 94-003 REVISION NO. 1	
Effective Date: March 31, 1994	Page 1 of 3

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DATE	REV. NO	DESCRIPTION
08/27/93	0	Describes the rationale for quantity ingestion of fruits and vegetables
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

Title: Ingestion of Homegrown Fruits and Vegetables	7312
SUPPLEMENT NO. 94-003 REVISION NO. 1	
Effective Date: March 31, 1994	Page 3 of 3

1.0 **OBJECTIVE**

This guidance is the rationale for quantity ingestion of fruits and vegetables given by the U.S. Environmental Protection Agency in the Exposure Factors Handbook, Part II (March 1990).

2.0 **SUPPLEMENTAL GUIDANCE**

Using the rationale given in the Exposure Factors Handbook, Part II (EPA 1990), there will be two fractions factored into the intake equation:

- Fraction of Consumption Rate:
  - .40 for vegetables
  - .30 for fruits

- Fraction of Time Homegrown Foods are Eaten:
  - .50 of time (or exposure frequency)

These factors will be used for all future FEMP risk assessments.

3.0 **SUPPORTING INFORMATION**

None.

4.0 **REFERENCES**

U.S. Environmental Protection Agency, March 1990, "Exposures Factor Handbook, Part II," U.S. EPA, Washington, DC, pgs. 1-9 and 1-10.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

POPULATION DISTRIBUTION

SUPPLEMENT NO. 94-004
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

Title: Population Distribution	7312
SUPPLEMENT NO. 94-004 REVISION NO. 1	
Effective Date: March 31, 1993	Page 1 of 3

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DATE	REV. NO	DESCRIPTION
09/14/93	0	Describes population distributions for use in all FEMP risk assessments
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

Title: Population Distribution	- 7312
SUPPLEMENT NO. 94-004 REVISION NO. 1	
Effective Date: March 31, 1993	Page 3 of 3

1.0 **OBJECTIVE**

The following population distribution information is taken from the Site-Wide Characterization Report (DOE 1993) and should be used in all FEMP risk assessments.

2.0 **SUPPLEMENTAL GUIDANCE**

- For the 1990 residential population distribution for a five mile radius, use Figure 2-24 and 2-25, Volume 1, Part I, Section 2.0, page 2-81 and 2-82, respectively.

- For the daytime residential/business population distribution, use Figure 2-25 and Table 2-15, Volume 1, Part I, Section 2.0, pages 2-83 and 2-84, respectively.

- For the projected residential population distribution for the year 2010, use Figure C.1-2 and Table C.1-3, Volume 4, Appendix C, pages C-6 and C-7, respectively.

3.0 **SUPPORTING INFORMATION**

Attached is the population distribution information described in 2.0 above.

4.0 **REFERENCES**

U.S. Department of Energy, 1993, "Site-Wide Characterization Report, Remedial Investigation and Feasibility Study, Fernald Environmental Management Project," U.S. DOE, Fernald Field Office, Fernald, OH.

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JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

USE OF DATA WITH MDA/SQL AND CRDL/CRQL

SUPPLEMENT NO. 94-005
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000029

Title: Use of Data With MDA/SQL and CRDL/CRQL	- 7312
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DATE	REV. NO	DESCRIPTION
09/15/93	0	Provides guidance for use of data when both MDA/SQLs and CRDL/CRQLs are used
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

Title: Use of Data With MDA/SQL and CRDL/CRQL	F-7312
SUPPLEMENT NO. 94-005 REVISION NO. 1	
Effective Date: March 31, 1994	Page 3 of 3

1.0 **OBJECTIVE**

New guidelines from the Fernald Environmental Management Project (FEMP) validation group have dictated a change in validation protocols. Previously, sample analytical results were reported at the contract required detection limit (CRDLs) for radionuclide parameters and contract required quantitation limit (CRQLs) for chemical parameters.

2.0 **SUPPLEMENTAL GUIDANCE**

The difference between the minimum detectable activity (MDA)/sample quantitation limits (SQLs) and the CRDLs/CRQLs vary from no difference to up to an order of magnitude difference. The impact of combining data sets validated to MDA/SQLs and those validated to CRDLs/CRQLs will need to be assessed in cases where the action level is close to the MDA/SQLs. This is consistent with the Risk Assessment Work Plan Addendum, which states (see references below):

> "A value of the SQL will be sought for each non-detected result. If SQLs cannot be obtained for chemical [or radionuclide] analytical results, the CRQL [or CRDL] will be used as the value of the SQL [or MDA]. The uncertainty introduced by this assumption will be evaluated, since the CRQL [or CRDL] may overestimate or underestimate the SQL (EPA 1989a)."

Therefore, when necessary, data sets which use a combination of MDA/SQLs and CRDL/CRQLs may be used in FEMP risk assessments; however, the potential impacts of using differing values for non-detects must be addressed in the uncertainties section of the risk assessment.

3.0 **SUPPORTING INFORMATION**

The new guidelines dictate that results will be validated to the MDA for radionuclide data and SQLs for chemical data. Also, the U.S. Environmental Protection Agency, Region V, prefers that one half of the MDA/SQLs be used for non-detects in the statistical analysis.

4.0 **REFERENCES**

U.S. Environmental Protection Agency, 1989, "Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A, Interim Final," EPA/540/1-89/002, EPA, Office of Emergency and Remedial Response, Washington, DC.

7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

EXPOSURE SCENARIOS, RECEPTORS, AND INPUT PARAMETERS

SUPPLEMENT NO. 94-006
REVISION NO. 3

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000033

Title: Exposure Scenarios and Input Parameters	7312
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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
10/19/93	0	Provides receptors, exposure pathways, parameter values, and intake equations for all future FEMP risk assessments
12/16/93	1	Change to replace recreational user with expanded trespasser, include a Great Miami River User receptor, use 95th percentile body surface areas, and break out exposures to soils and sediments.
03/04/94	2	Change to reflect changes to input parameters which have occurred in response to U.S. Environmental Protection Agency (EPA) and Ohio EPA comments
03/31/94	3	Change for submittal to U.S. Environmental Protection Agency

1.0 **OBJECTIVE**

This guidance reflects changes to input parameters which have occurred in response to U.S. Environmental Protection Agency (EPA) and Ohio EPA comments.

2.0 **SUPPLEMENTAL GUIDANCE**

During a February 24, 1994 meeting with EPA, the use of 95th percentile body surface areas in conjunction with average body weights were discussed. It was concluded that the inhalation rates being used for children (0.5 m^3/hr) and youth and adults (0.83 m^3/hr) are reasonable and will be used in future reports. It was also agreed that the mixing of a 95th percentile body surface area with an average body weight is physiologically incorrect. EPA will confer with the authors of the skin surface area parameters to resolve this issue. Until further guidance is received from EPA, the 95th percentile values will be used.

The expanded trespasser will continue to be addressed by all operable units. An array of trespassing/recreational exposure scenarios will be developed for Operable Unit 5, which will evaluate both intrusive and non-intrusive use of the FEMP property. Certain off-property receptors, specific to the area, will also be developed for Operable Unit 5. Specific exposure factors for these receptors will be developed at a later date.

Information provided from Ohio EPA and the Ohio Department of Natural Resources in March 1994 indicates that water from the Great Miami River is currently being used for agricultural purposes. No available information indicates that Great Miami River water is being used as a drinking water source or for household use. However, potential risks to these pathways will be evaluated. It is extremely unlikely that a receptor is exposed to Great Miami River water through all pathways. Therefore, for a realistic evaluation of risk to the Great Miami River user, risk summary tables will present risks from recreational use of the Great Miami River (i.e., swimming and fishing), risks from agricultural use of Great Miami River water, and risks from household use of Great Miami River water.

3.0 **SUPPORTING INFORMATION**

Attached are exposure scenarios and exposure input parameter tables. The receptors, exposure pathways, parameter values, and intake equations listed in the tables should be used in future RI/FS documents.

4.0 **REFERENCES**

None.

EXPOSURE SCENARIOS AND EXPOSURE INPUT PARAMETERS

The receptors, exposure pathways, parameter values and intake equations listed below should be used in future RI/FS documents.

Inhalation of Particulates (Chemical)

$$Intake\ (mg/kg\text{-}day) = \frac{C_a \times IR \times ET \times EF \times ED}{BW \times AT} \quad (1)$$

Inhalation of Radionuclides

$$Intake\ (pCi) = C_a \times IR \times ET \times EF \times ED \quad (2)$$

Parameters	RME On-property farmer	CT . On-property farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Tres-passing Youth	User of GMR	On-prop. home builder
BW (kg)	70[a]	70[a]	15[a]	70[a]	15[a]	70[a]	70[a]	43[a]	NA	70[a]
IR (m^3/hr)	0.83[a]	0.83[a]	0.5[x]	0.83[a]	0.5[x]	2.5[f]	2.5[f]	0.83[a]	NA	2.5[f]
ET (hr/day)	5.7[a]	4.2[g]	2[p]	5.7[a]	2[p]	2[g]	8[f]	4[n]	NA	8.0[g]
EF (days/yr)	350[f]	275[g]	350[f]	350[f]	350[f]	250[f]	OU * specific	52[n]	NA	175[g]
ED (yrs)	70[g,u]	9[a]	6[a]	70[g,u]	6[a]	25[a]	25[a]	12[g]	NA	1[a]
ATn (days)	25550	3285[a]	2190[a]	25550	2190[a]	9125[a]	9125[a]	4380[a]	NA	175[a]
ATc (days)	25550[a]	25550[a]	25550	25550	25550	25550	25550	25550	NA	25550[a]
C_a (mg/m^3), (pCi/m^3)	csv	csv	csv	csv	csv	csv	csv	csv	NA	csv

BW body weight
IR inhalation rate
ET exposure time
EF exposure frequency
ATn averaging time for noncarcinogens
ATc averaging time for carcinogens
C_a concentration of i^{th} contaminant in air
csc chemical specific value

* assumes OU specific values: 35 days/yr for OU 1,2,4; and 250 days/yr for OU 3,5

000037

Inhalation of Indoor Concentrations of Radon

$$Intake\ (pCi) = C_{Rn} \times EF \times ED \times IR \qquad (3)$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Groundskeeper	Trespassing Youth	User of GMR	On-property home builder
BW (kg)	70[e]	70[e]	15[e]	NA	NA	NA	NA	NA	NA	NA
IR (m3/day)	15[h]	15[h]	15[h]	NA	NA	NA	NA	NA	NA	NA
EF (days/yr)	350[f]	275[g]	350[f]	NA	NA	NA	NA	NA	NA	NA
ED (yrs)	70	9[e]	6[e]	NA	NA	NA	NA	NA	NA	NA
C_{Rn} (pCi/m^3)	csv	csv	csv	NA	NA	NA	NA	NA	NA	NA

C_{Rn} Concentration of Radon Indoors
NA Not Applicable
csv Contaminant Specific Value
IR Inhalation Rate
EF Exposure Frequency
ED Eposure Duration
csv contanimant specific value

000038

2 3 2 4

Ingestion of soil/sediments

(chemicals)

$$Intake\ (mg/kg\text{-}day) = \frac{C_s \times CF \times IR \times FI \times EF \times ED}{BW \times AT} \quad (4)$$

(Radionuclides)

$$Intake\ (pCi) = C_s \times CF \times IR \times FI \times EF \times ED \quad (5)$$

Parameters	RME On-prop. farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Tres-passing Youth***	User of GMR (sediments only)**	On-prop. home builder
BW (kg)	70[e]	70[e]	15[e]	NA	NA	NA	70[e]	43[e]	70[e]	70[e]
IR (mg/day)	180[g]	122[g]	200[h]	NA	NA	NA	100[h]	100[h]	100[h]	480[f]
FI (unitless)	1.0[j]	1.0[j]	1.0[j]	NA	NA	NA	1.0[j]	0.19 from soil[f] 0.06 from sed.[j]	0.17[f]	1.0[j]
EF (days/yr)	350[f]	275[g]	350[f]	NA	NA	NA	OU * specific	52[n]	7[f]	175[e]
ED (yrs)	70[g,u]	9[t]	6[e]	NA	NA	NA	25[t]	12[g]	30[g]	1[e]
ATn (days)	25550	3285	2190[e]	NA	NA	NA	9125[e]	4380[e]	10950	175[e]
ATc (days)	25550[e]	25550	25550[e]	NA	NA	NA	25550[e]	25550[e]	25550	25550[e]
C_s (mg/kg), (pCi/g)	csv	csv	csv	NA	NA	NA	csv	csv	csv	csv
CF rads (g/mg)	10^{-3}	10^{-3}	10^{-3}	NA	NA	NA	10^{-3}	10^{-3}	10^{-3}	10^{-3}
CF chem (kg/mg)	10^{-6}	10^{-6}	10^{-6}	NA	NA	NA	10^{-6}	10^{-6}	10^{-6}	10^{-6}

CF conversion factors for radionuclides and chemicals

* 35 days/yr for OUs 1,2, and 4; 250 days/yr for OUs 3 and 5

** The GMR User will be evaluated for exposure to sediments only (due to contact with the GMR)

*** The trespassing youth may be exposed to both sediments and soil. It is assumed that while the trespassing youth is on site, he/she spends one hour playing in surface water.

000039

Ingestion of Drinking Water

$$\text{Intake (pCi)} = C_w \frac{\sum C_w IR \times IF \quad EF \quad ED}{BW \times AT} \qquad \text{Intake (mg/kg-day)} \qquad (6)\ (7)$$

Parameters	RME On-prop. farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	User of GMR	On-property home builder
BW (kg)	70[e]	70[e]	15[e]	70[e]	15[e]	NA	NA	NA	70	NA
IR (L/day)	2[e]	1.4[e]	1.0[f]	2[e]	1.0[f]	NA	NA	NA	2.0a	NA
EF (days/yr)	350[f]	275[g]	350[f]	350[f]	350[f]	NA	NA	NA	350	NA
ED (yrs)	70[g]	9[f]	6[e]	70	6	NA	NA	NA	70	NA
ATn (days)	25550	3285	2190	25550	2190	NA	NA	NA	25550	NA
ATc (days)	25550[e]	25550	25550	25550	25550	NA	NA	NA	25550	NA
C_w (pCi/L), (mg/L)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA

IR Ingestion Rate
FI Fraction Ingested from Source
C_w Concentration of i^{th} Contaminant in Drinking Water

000040

23129

Inhalation of Volatiles Released from Water by Showering and Household Uses (including radon)

$$Intake(mg/kg\text{-}day) = \frac{C_w \times IR \times K \times EF \times ED}{BW \times AT} \quad (8)$$

Parameters	RME On-prop. farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	User of GMR	On-property home builder
BW (kg)	70[e]	70[e]	15[e]	70[e]	15[e]	NA	NA	NA	70	NA
IR (m^3/day)	15[h]	15[h]	15[h]	15[h]	15[h]	NA	NA	NA	15[h]	NA
EF (days/yr)	350[f]	275[g]	350[f]	350[f]	350[f]	NA	NA	NA	350[f]	NA
ED (yrs)	70[g]	9[f]	6[e]	70	6[e]	NA	NA	NA	70[g]	NA
ATn (days)	25550	3285[e]	2190[e]	25550	2190[e]	NA	NA	NA	25550	NA
ATc (days)	25550[e]	25550[e]	25550[e]	25550[e]	25550[e]	NA	NA	NA	25550	NA
K (L/m^3)	.5[k]	.5[k]	.5[k]	.5[k]	.5[k]	NA	NA	NA	0.5[k]	NA
Cw (mg/L)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA

C_w Concentration of ith Contaminant
K Volitization Factor of 0.0005 X 1000 L/m^3

000041

Dermal contact with soil

$$\text{Absorbed dose (mg/kg-day)} = \frac{C_s \times CF \times SA \times AF \times ABS \times EF \times ED}{BW \times AT} \quad (9)$$

Parameters	RME On-prop. farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	** User of GMR	On-property home builder
BW (kg)	70[e]	70[e]	15[e]	NA	NA	NA	70[e]	43[e]	NA	70[e]
SA (cm^2)	5750[f]	5000[f]	2000[f]	NA	NA	NA	5750[f]	4200[f]	NA	5750[f]
EF (events/yr)	350[f]	275[g]	350[f]	NA	NA	NA	OU * specific	52[n]	NA	175[a]
ED (yrs)	70[g]	9[e]	6[e]	NA	NA	NA	25[e]	12[g]	NA	1[e]
ATn (days)	25550	3285	2190	NA	NA	NA	9125	4380	NA	175
ATc (days)	25550[e]	25550	25550	NA	NA	NA	25550	25550	NA	25550[e]
ABS (unitless)	csv	csv	csv	NA	NA	NA	csv	csv	NA	CSV
C_s (mg/kg)	csv	csv	csv	NA	NA	NA	csv	csv	NA	CSV
CF (kg/mg)	10^{-6}	10^{-6}	10^{-6}	NA	NA	NA	10^{-6}	10^{-6}	NA	10^{-6}
AF (mg/cm^2)	1.0[f]	0.2[f]	1.0	NA	NA	NA	1.0	1.0	NA	1.0

Cs concentration of i^{th} contaminant in soil
AF skin adherence factor
ABS absorption factor
SA surface area of body exposed

* assumes 35 days/yr for OUs 1,2, and 4; and 250 days/yr for OUs 3 and 5
** The GMR recreational user will be evaluated for exposure to sediment, not soils

0000482

2 3 1 2

Dermal contact with sediment

$$\text{Absorbed dose (mg/kg-day)} = \frac{C_s \times CF \times SA \times AF \times ABS \times EF \times ED}{BW \times AT} \quad (10)$$

Parameters	RME On-prop. farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	** User of GMR	On-property home builder
BW (kg)	NA	NA	NA	NA	NA	NA	NA	43[e]	70[e]	NA
SA (cm^2)	NA	NA	NA	NA	NA	NA	NA	5130[f]	5750	NA
EF (events/yr)	NA	NA	NA	NA	NA	NA	NA	52[n]	7[i]	NA
ED (yrs)	NA	NA	NA	NA	NA	NA	NA	12[g]	30[d]	NA
ATn (days)	NA	NA	NA	NA	NA	NA	NA	4380	10950	NA
ATc (days)	NA	NA	NA	NA	NA	NA	NA	25550	25550	NA
ABS (unitless)	NA	NA	NA	NA	NA	NA	NA	csv	csv	NA
C_s (mg/kg)	NA	NA	NA	NA	NA	NA	NA	csv	csv	NA
CF (kg/mg)	NA	NA	NA	NA	NA	NA	NA	10^{-6}	10^{-6}	NA
AF (mg/cm^2)	NA	NA	NA	NA	NA	NA	NA	1.0	1.0	NA

Cs concentration of i^{th} contaminant in soil
AF skin adherence factor
ABS absorption factor
SA surface area of body exposed

** The GMR recreational user will be evaluated for exposure to sediment, not soils

000043

2 3 1 2

Dermal contact with surface water while wading or swimming

$$\text{Absorbed dose } (mg/kg\text{-}day) = \frac{SA \times DA_e \times EF \times ED}{BW \times AT} \quad (11)$$

DA_e can be calculated as follows: (see EPA 1992, Dermal Exposure Assessment: Principles and Applications, p. 5-51:

$$\text{IF } ET<t^*, \text{ then: } DA_e\ (mg/cm^2\text{-}event) = 2K_p \times C_{ws} \times CF \sqrt{\frac{6 \times \tau \times ET}{3.14}} \quad (12)$$

$$\text{IF } ET>t^*, \text{ then: } DA_e\ (mg/cm^2\text{-}event) = K_p \times C_{ws} \times CF \left[\frac{ET}{1+B} + 2\tau \times \left(\frac{1+3B}{1+B}\right)\right] \quad (13)$$

where: K_p = Permeability Coefficient (cm/hr)
τ = Lag time (hr)
t^* = time (hr)
B = partioning property of contaminant (unitless)
get K_p, τ, t^*, and B from Table 5-8, in the 1992 Dermal Exposure Assessment: Principles and Applications

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	Users of GMR	On-property home builder
BW (kg)	NA	NA	NA	NA	NA	NA	NA	43[e]	70a	NA
SA (cm^2)	NA	NA	NA	NA	NA	NA	NA	5130[f]	23,000[f]	NA
ET (hr/event)	NA	NA	NA	NA	NA	NA	NA	1.0[f]	2.6[f]	NA
EF (events/yr)	NA	NA	NA	NA	NA	NA	NA	52[f]	7[f]	NA
ED (yrs)	NA	NA	NA	NA	NA	NA	NA	12[g]	30d	NA
ATn (days)	NA	NA	NA	NA	NA	NA	NA	4380[e]	10950	NA
ATc (days)	NA	NA	NA	NA	NA	NA	NA	25550[e]	25550	NA
K_p (cm/hr)	NA	NA	NA	NA	NA	NA	NA	csv	csv	NA
CF (L/cm^3)	NA	NA	NA	NA	NA	NA	NA	0.001	0.001	NA
C_{ws}	NA	NA	NA	NA	NA	NA	NA	csv	csv	NA

SA Skin Surface Area Exposed
C_{ws} Concentration of i^{th} Contaminant in Surface Water
csv chemical specific value

000044

Incidental Ingestion of Surface Water while wading or swimming

$$Intake\ (pCi) = C_{sw} \times IR \times ET \times EF \times ED \qquad (14)$$

$$Intake\ (mg/kg\text{-}day) = \frac{C_{ws} \times IR \times ET \times EF \times ED}{BW \times AT}$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Tres-passing Youth	Users of GMR	On-prop. home builder
BW (kg)	NA	NA	NA	NA	NA	NA	NA	43[e]	70[d]	NA
IR (L/hr)	NA	NA	NA	NA	NA	NA	NA	0.035[e]	0.05[d]	NA
ET (hrs/event)	NA	NA	NA	NA	NA	NA	NA	1.0[e]	2.6[d]	NA
EF (event/yr)	NA	NA	NA	NA	NA	NA	NA	52[e]	7[d]	NA
ED (yrs)	NA	NA	NA	NA	NA	NA	NA	12[e]	30	NA
ATn (days)	NA	NA	NA	NA	NA	NA	NA	4380	10950	NA
ATc (days)	NA	NA	NA	NA	NA	NA	NA	25550	25550	NA
C_{ws} (mg/L) (pCi/L)	NA	NA	NA	NA	NA	NA	NA	csv	csv	NA

C_{ws} Concentration of ith Contaminant in surface water.
IR Ingestion Rate

0000495

Direct Irradiation from soils/sediment

$$(pCi\text{-}yr/g) = C_s \times CF \times EF \times ED \times (ET_{out} \times (1-SH_o) + ET_i \times (1-SH_i)) \quad (16)$$

Parameter	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	** Trespassing Youth	User of GMR	On-prop. home builder
ET_{in} (hr/day)	18.3[e]	19.8[g]	22[p]	NA	NA	NA	NA	NA	NA	4[e]
ET_{out} (hr/day)	5.7[e]	4.2[g]	2[p]	NA	NA	2[g]	8[f]	3 from soil[g] 1 from sed.[g]	2.6[f] (from sediment only)	4[e]
EF (day/yr)	350[f]	275[g]	350[f]	NA	NA	250[F]	OU * specific	52[n]	7[l]	175[e]
ED (yrs)	70	9[e]	6[e]	NA	NA	25[e]	25[e]	12[g]	70	1[e]
SH_i unitless	0.5[m]	0.5[m]	0.5[m]	NA	NA	NA	NA	NA	0.5[m]	0.5[m]
SH_o unitless	0[m]	0[m]	0	NA	NA	0	0	0	0/0[m]	0[m]
C_s (pCi/g)	csv	csv	csv	NA	NA	csv	csv	csv	csv	csv
CF (yr/hr)	1.14E-4	1.14E-4	1.14E-4	NA	NA	1.14E-4	1.14E-4	1.14E-4	1.14E-4	1.14E-4

ET_{in} Exposure Time Indoors
ET_{out} Exposure Time Outdoors
SH_i Shielding Factor Indoors
SH_o Shielding Factor Outdoors
C_s Concentration of i^{th} Contaminant in Soil
CF Conversion Factor

***assumes 35 days/yr for OUs 1,2, and 4; and 250 days/yr for OUs 3 and 5.**

Note: the trespassing youth is irradiated from both soil and sediments. Therefore, calculations for both media should be performed and the 4 hr exposure time should be divided proportionately to represent exposure to both (ie 3 hrs for soil, 1 hr for sediment)

Dermal Contact While Bathing

$$Total\ Absorbed\ dose\ (AB_w)\ (mg/kg\text{-}day) = \frac{DA_e \times SA \times EF \times ED}{BW \times AT} \qquad (17)$$

DA_e can be calculated as follows (see Dermal Exposure Assessment: EPA 1992, Principles and Applications, p. 5-51:

$$IF\ ET<t^*,\ then:\ DA_e\ (mg/cm^2\text{-}event) = 2K_p \times C_{ws} \times CF \sqrt{\left(\frac{6 \times \tau \times ET}{3.14}\right)} \qquad (18)$$

$$IF\ ET>t^*,\ then:\ DA_e\ (mg/cm^2\text{-}event) = K_p \times C_{ws} \times CF \left(\frac{ET}{1+B} + 2\tau \times \left(\frac{1+3B}{1+B}\right)\right) \qquad (19)$$

where: K_p = Permeability Coefficient (cm/hr)
DA_e = Dermally absorbed dose per event (mg/cm2-event)
τ = Lag time (hr)
t^* = time (hr)
B = partitioning property of constituent (unitless)
get K_p, τ, t^*, and B from Table 5-8, in the 1992 Dermal Exposure Assessment: Principles and Applications

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Trespassing Youth	Users of GMR	On-prop. home builder
BW (kg)	70[a]	70[a]	15[a]	70[a]	15[a]	NA	NA	NA	70	NA
SA (cm^2)	23,000[f]	20,000[f]	8000[f]	23,000[f]	8000[f]	NA	NA	NA	23,000	NA
DA_e[n](event)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA
CF (L/cm3)	0.001	0.001	0.001	0.001	0.001	NA	NA	NA	0.001	NA
ET (hr/day)	0.25[f]	0.17[f]	0.25[f]	0.25[f]	0.25[f]	NA	NA	NA	0.25	NA
EF (days/yr)	350[f]	275[g]	350[f]	350[f]	350[f]	NA	NA	NA	350	NA
ED (yrs)	70	9[a]	6[a]	70	6	NA	NA	NA	70	NA
ATn (days)	25550	3285	2190	25550	2190	NA	NA	NA	25550	NA
ATc (days)	25550[a]	25550	25550	25550	25550	NA	NA	NA	25550	NA

SA Skin surface area exposed (total body)
DA_e Dose absorbed per event

0000427

2312

Ingestion of Homegrown Fruits and Vegetables

$$Intake\ (chemicals)\ (mg/kg\text{-}day) = \frac{C_{iv} \times CF \times IR \times FI_t \times EF \times ED}{BW \times AT} \quad (20)$$

$$Intake\ (radionuclides)\ (pCi) = C_{iv} \times IR \times FI_t \times EF \times ED \quad (21)$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Groundskeeper	Trespassing Youth	Users of GMR	On-prop. home builder
BW (kg)	70[e]	70[e]	15[e]	70[e]	15[e]	NA	NA	NA	70	NA
IR (g/day)	122[1,t]	78[t]	106[e,t]	122[1,t]	106[e,t]	NA	NA	NA	122[1,t]	NA
FI_t	0.5[t]	0.5[t]	0.5[t]	0.5[t]	0.5[t]	NA	NA	NA	0.5[t]	NA
EF (days/yr)	350[t]	275[e]	350[t]	350[t]	350[t]	NA	NA	NA	350	NA
ED (yrs)	70	9[t]	6	70	6	NA	NA	NA	70	NA
ATn (days)	25550	3285	2190	25550	2190	NA	NA	NA	25550	NA
ATc (days)	25550[e]	25550	25550	25550	25550	NA	NA	NA	25550	NA
CF (kg/g)	0.001	0.001	0.001	0.001	0.001	NA	NA	NA	0.001	NA
C_{iv} (mg/kg), (pCi/g)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA

CF Conversion Factors
IR Ingestion Rate- (Fraction of Intake from Source is Included)
FI_t Fraction of year (time) that homegrown produce are eaten
C_{iv} Concentration of i^{th} Contaminant in Fruits and Vegetables

000048

2312

Ingestion of Home Produced Meats

$$Intake\ (chemicals)\ (mg/kg\text{-}day) = \frac{C_{iB} \times CF \times IR \times EF \times ED}{BW \times AT} \quad (22)$$

$$Intake\ (radionuclides)\ (pCi) = C_{iB} \times IR \times EF \times ED \quad (23)$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Tres-passing Youth	Users of GMR adult/youth	On-prop. home builder
BW (kg)	70[a]	70[a]	15[a]	70[a]	15[a]	NA	NA	NA	70	NA
IR (g/day)	75[1,a]	50[g]	29[a,t]	75[a,t]	29[a,t]	NA	NA	NA	75[1,a]	NA
EF (days/yr)	350[1]	275[g]	350[1]	350[1]	350[1]	NA	NA	NA	350[1]	NA
ED (yrs)	70	9[a]	6[a]	70	6[a]	NA	NA	NA	70	NA
ATn (days)	25550	3285	2190	25550	2190	NA	NA	NA	25550	NA
ATc (days)	25550[a]	25550	25550	25550	25550	NA	NA	NA	25550	NA
CF (kg/g)	0.001	0.001	0.001	0.001	0.001	NA	NA	NA	0.001	NA
C_{iA} (mg/kg), (pCi/g)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA

C_{iA} Concentration of i^{th} Contaminant in meat product
IR Igestion Rate (Includes Fraction from Home Produced Meat)
CF Conversion Factor

0000049

Ingestion of Milk

$$Intake\ (chemicals)\ (mg/kg\text{-}day) = \frac{C_{iM} \times IR \times EF \times ED}{BW \times AT} \quad (24)$$

$$Intake\ (Radionuclides)\ (pCi) = C_{iM} \times IR \times EF \times ED \quad (25)$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Grounds-keeper	Tres-passing Youth	Users of GMR	On-prop. home builder
BW (kg)	70[a]	70[a]	15[a]	70[a]	15[a]	NA	NA	NA	70[a]	NA
IR (L/day)	0.3[t]	0.16[t]	0.68[a,t]	0.3[t]	0.68[a,t]	NA	NA	NA	0.3[t]	NA
EF (days/yr)	350[t]	275[g]	350[t]	350[t]	350[t]	NA	NA	NA	350[t]	NA
ED (yrs)	70	9[a]	6[a]	70	6	NA	NA	NA	70	NA
ATn (days)	25550	3285	2190	25550	2190	NA	NA	NA	25550	NA
ATc (days)	25550[a]	25550	25550	25550	25550	NA	NA	NA	25550	NA
C_{iM} (mg/L), (pCi/L)	csv	csv	csv	csv	csv	NA	NA	NA	csv	NA

C_{iM} Concentration of i^{th} Contaminant in Milk Products
IR Ingestion Rate (includes fraction of milk products produced at home)

000050

2132

Ingestion of Fish

$$Intake\ (chemicals)\ (mg/kg\text{-}day) = \frac{C_{iF} \times CF \times IR \times EF \times ED}{BW \times AT} \quad (26)$$

$$Intake\ (Radionuclides)\ (pCi) = C_{iF} \times IR \times EF \times ED \quad (27)$$

Parameters	RME On-prop farmer	CT On-prop. farmer	On-prop. child	Off-prop. Farmer	Off-prop. child	Visitor	Groundskeeper	Trespassing Youth	Use of GMR	On-prop. home builder
BW (kg)	NA	NA	NA	NA	NA	NA	NA	NA	70[a]	NA
IR (g/day)	NA	NA	NA	NA	NA	NA	NA	NA	54[a]	NA
EF (days/yr)	NA	NA	NA	NA	NA	NA	NA	NA	122[a]	NA
ED (yrs)	NA	NA	NA	NA	NA	NA	NA	NA	70[a]	NA
ATn (days)	NA	NA	NA	NA	NA	NA	NA	NA	25550	NA
ATc (days)	NA	NA	NA	NA	NA	NA	NA	NA	25550	NA
CF (kg/g)	NA	NA	NA	NA	NA	NA	NA	NA	0.001	NA
C_{iF} (mg/kg) (pCi/kg)	NA	NA	NA	NA	NA	NA	NA	NA	CSV	NA

CF conversion factor
C_{iF} Concentration of i^{th} Contaminant in Fish.
IR Ingestion Rate

000051

2-1-94

EXPANDED TRESPASSER SCENARIO

The following are the exposure pathways, parameter values and intake equations for the expanded trespasser to be used in future RI/FS documents. Either age-adjusted or separate equations may be used for the adult and older child.

Inhalation of Particulates (Chemical)

Age Adjusted Intake via inhalation (I_{AA}) (m^3/kg-day)

$$I_{AA} = \left(\frac{ET_{oc} \times EF_{oc} \times ED_{oc} \times IR}{BW_{oc} \times AT_{oc}}\right) + \left(\frac{ET_a \times EF_a \times ED_a \times IR}{BW_a \times AT_a}\right) \quad (28)$$

$$Intake\ (mg/kg\text{-}day) = C_a \times I_{AA} \quad (29)$$

Intake (pCi) =

$$(C_a \times ET_a \times EF_a \times ED_a \times IR) + (C_a \times ET_{oc} \times EF_{oc} \times ED_{oc}\ IR) \quad (30)$$

Parameters	Expanded Trespasser older child (oc)	Expanded Trespasser adult (a)
BW (kg)	43[a]	70[a]
IR (m^3/hr)	0.83[a]	0.83[a]
ET (hr/day)	2[b]	1[b]
EF (days/yr)	110[c]	40[c]
ED (yrs)	12	32
ATn (days)	4380	11680
ATc (days)	25550	25550
C_a (mg/m^3), (pCi/m^3)	csv	csv

BW	body weight	csv	contaminant specific value
IR	inhalation rate		
ET	exposure time		
EF	exposure frequency		
ATn	averaging time for noncarcinogens		
ATc	averaging time for carcinogens		
C_a	concentration of i^{th} contaminant in air		

250052

2-32

Ingestion of Soil

Age adjusted Intake via ingestion (I_{AA}) (mg/kg-day) =

$$I_{AA} = \left(\frac{FI_{oc} \times EF_{oc} \times ED_{oc} \times IR}{BW_{oc} \times AT_{oc}}\right) + \left(\frac{FI_{a} \times EF_{a} \times ED_{a} \times IR}{BW_{a} \times AT_{a}}\right) \quad (31)$$

Intake (mg/kg-day) =

$$C_s \times I_{AA} \times CF \quad (32)$$

Intake (pCi) =

$$C_s \times CF(FI_a \times EF_a \times ED_a \times IR) + (FI_{oc} \times EF_{oc} \times ED_{oc}\ IR) \quad (33)$$

***Ingestion of Sediment C**

chemicals

$$I = \frac{C_s \times CF \times IR_{oc} \times FI_{oc} \times EF_{oc} \times ED}{BW_{oc} \times AT_{oc}} \quad (34)$$

radionuclides

$$I = C_s \times CF \times IR_{oc} \times FI_{oc} \times EF_{oc} \times ED_{oc}$$

Parameters	Expanded Trespasser older child	Expanded Trespasser adult	Expanded trespasserr - Older child
BW (kg)	43[a]	70[a]	43[a]
IR (mg/day)	100[b]	100[b]	100[b]
FI (unitless)	0.125[c]	0.125[c]	0.063[c]
EF (days/yr)	110[d]	40[d]	52[c]
ED (yrs)	12[e]	32	12
ATn (days)	4380	11680	4380
ATc (days)	25550	25550	25550
C_s (mg/kg), (pCi/g)	csv	csv	csv
CF rads (g/mg)	1.0 E-3	1.0 E-3	1.0 E-3
CF chem (kg/mg)	1.0 E-6	1.0 E-6	1.0 E-6

CF conversion factors for radionuclides and chemicals

• we are assuming that only the older child wades in Paddys Run

000053

Dermal Contact with soil

Age adjusted surface area factor (SAF_{AA})(cm^2/kg-day) =

$$SAF_{AA} = \left(\frac{EF_{oc} \times ED_{oc} \times SA_{oc}}{BW_{oc} \times AT_{oc}}\right) + \left(\frac{EF_a \times ED_a \times SA_a}{BW_a \times AT_a}\right) \quad (36)$$

Intake or Absorbed dose (mg/kg-day) =

$$C_s \times SAF_{AA} \times CF \times AF \times ABS \quad (38)$$

Dermal Contact with Sediment

Absorbed dose(mg/kg-day) =

$$\frac{C_s \times CF \times EF_{oc} \times ED_{oc} \times SA_{oc} \times AF \times ABS}{BW_{oc} \times AT_{oc}} \quad (39)$$

Parameters	Expanded Trespasser older child	Expanded Trespasser adult	Expanded Trespasser (older child)
BW (kg)	43[a]	70[a]	43
SA (cm^2)	4200[a]	5750[a]	5130[a]
EF (events/yr)	110[a]	40[c]	52[c]
ED (yrs)	12[b]	32[b]	12
ATn (days)	4380[a]	11680[a]	4380
ATc (days)	25550[a]	25550[a]	25550
ABS (unitless)	csv	csv	csv
C_s (mg/kg)	csv	csv	csv
CF (kg/mg)	10^{-6}	10^{-6}	10-6
AF (mg/cm^2)	1.0	1.0	1.0

Cs concentration of i^{th} contaminant in soil
AF skin adherence factor
ABS absorption factor
SA surface area of body exposed

Dermal contact with surface water

$$Absorbed\ dose\ (mg/kg\text{-}day) = \frac{SA \times DA_e \times EF \times ED}{BW \times AT} \quad (40)$$

DA_e can be calculated as follows: (see EPA 1992, Dermal Exposure Assessment: Principles and Applications, p. 5-51:

$$IF\ ET < t^*,\ then:\ DA_e\ (mg/cm^2\text{-}event) = 2K_p \times C_{ws} \times CF \sqrt{\left(\frac{6 \times \tau \times ET}{3.14}\right)} \quad (41)$$

$$IF\ ET > t^*,\ then:\ DA_e\ (mg/cm^2\text{-}event) = K_p \times C_{ws} \times CF \left(\frac{ET}{1+B} + 2\tau \times \left(\frac{1+3B}{1+B}\right)\right) \quad (42)$$

where: K_p = Permeability Coefficient (cm/hr)
τ = Lag time (hr)
t^* = time (hr)
B = bio-uptake
get K_p, τ, t^*, and B from Table 5-8, in the 1992 Dermal Exposure Assessment: Principles and Applications

Parameters	Expanded Trespasser older child [oc]	Expanded Trespasser adult [a]
BW (kg)	43*	NA
SA (cm^2)	5130*	NA
ET (hr/event)	1.0*	NA
EF (events/yr)	52	NA
ED (yrs)	12*	NA
ATn (days)	4380	NA
ATc (days)	25550*	NA
K_p (cm/hr)	csv	NA
CF (L/cm^3)	0.001	NA
C_{ws}	csv	NA

SA Skin Surface Area Exposed
C_{ws} Concentration of i^{th} Contaminant in Surface Water
csv chemical specific value

* we are assuming that only the older child wades in Paddys Run

Incidental Ingestion of Surface Water

$$Intake\ (pCi) = C_{ws} \times EF_{oc} \times ED_{oc}\ IR \qquad (43)$$

$$Intake\ (mg/kg\text{-}day) = \frac{C_{ws} \times IR_{oc} \times EF_{oc} \times ED_{oc}}{BW_{oc} \times AT}$$

Parameters	Expanded Trespasser older child	Expanded Trespasser adult
BW (kg)	43*	NA
IR (L/event)	0.035*	NA
EF (events/yr)	52*	NA
ED (yrs)	12	NA
ATn (days)	4380	NA
ATc (days)	25550	NA
C_{ws} (mg/L) (pCi/L)	csv	NA

C_{ws} Concentration of ith Contaminant in surface water.
IR Ingestion Rate

* we are assuming that only the older child wades in Paddys Run

950000

2 1 3 9

Direct Irradiation from Soils Age Adjusted External Radiation (pCi-yr/g) = $CF*(1-SH_o)(C_s*ET_{out_{oc}}*EF_{oc}*ED_{oc})+(C_s*ET_{out_a}*EF_a*ED_a)$ (45)			*Direct Irradiation from Sediment $C_s \times CF \times EF \times ED \times ET_o \times (1-SH_o)$
Parameter	**Expanded Trespasser older child**	**Expanded Trespasser adult**	**Expanded Trespasser - older child**
ET_{in} (hr/day)	NA	NA	NA
ET_{out} (hr/day)	2[b]	1[b]	1[b]
EF (day/yr)	110[d]	40[d]	52
ED (yrs)	12[b]	32[b]	12
SH_i unitless	NA	NA	NA
SH_o unitless	0[m]	0[m]	0[m]
C_s (pCi/g)	csv	csv	csv
CF (yr/hr)	1.1E-4	1.1E-4	1.1 E-4

ET_{in} Exposure Time Indoors
ET_{out} Exposure Time Outdoors
SH_i Shielding Factor Indoors
SH_o Shielding Factor Outdoors
C_s Concentration of i^{th} Contaminant in Soil
CF Conversion Factor

* it is assumed that only the older child (ages 6-18) will play in Paddys Run and therefore be exposed to sediment

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[a]EPA 1989, EPA/540/1-89/002 RAGS, Vol. 1, Part A
[b]Assumes the average stay is 2 hours for the older child and 1 hour for the adult. These parameters are consistent with information from Butler County Department of Recreation. Assumes an individual will use site over a period 44 years.
[c]Assumes an adult visits the site 1 hour/day for 40 days/yr (one day/week for 30 weeks plus 10 days for additional use). Assumes older child uses facility approximately 110 days/yr (using the site from April through October for 3 days per week for 30 weeks: an additional 20 days were added to allow for other visits. This guidance was provided by USEPA Region V.
[d]Assumptions for recreational use of the GMR: assumes user swims in the river over a period of 30 years
[e]Assumes farmer works 2000 hrs/yr outdoors
[f]EPA OSWER directive 9285.6-03, Standard Default Exposure Factors
[g]EPA Region V guidance, ET, ED, and soil ingestion rate for CT receptor are from personal communication between Mike Bollenbacher and Pat Van Leuwen, inhalation rates and soil ingestion rates for the farmers are from OU4 RI comments and responses, stating that the soil ingestion rate of 180 mg/day represents an age and occupational adjusted value. (See Operable Unit 4 RI)
[h]EPA 1991, OSWER directive 9285.7-0113 RAGS, Vol. 1, Part B
[i]EPA Region V guidance, based on fraction of waking hours (16 hrs) spent on or near source (ie.: 2/16 = 0.125)
[j]Based on fraction of day spent on site, or fraction of time consuming from source
[k]Using the Andelman Model 1990, it is assumed that half the concentration of volatile chemicals in water transfer to air. EPA 1991 RAGS, Vol.1, Part B, p.20-22
[l]EPA 1992, EPA/600/8-91/011B, Dermal Exposure Assessment: Principles and Applications , SAs are from section 8.4
[m]USNRC 1977, Regulatory Guide 1.109, assumes an indoor shielding factor of 0.5 and no shielding outdoors
[n]Guidance from EPA Region V, recommendation from Pat Van Leuwan that the youth will trespass on site approximately 3days/wk from June - August, plus 1 day/wk in April, May, September and October, for 4 hr/day (of which one hour is spent playing in Paddys Run.
[o]Assumes worker spends 175, 8-hr days building a house. An average of 50% of the working hours are spent in outdoor construction and 50% on indoor construction
[p]Assumes a small resident child spends 700 hrs/yr outdoors
[q]Assumes a visitor/delivery person spends 2 hrs/day on site
[r]Assumes a wading scenario because Paddy's Run is too shallow for swimming, therefore approximately 31% of total 95th percentile body surface exposed, for feet, lower legs, hands and forearms. EF assumes that the of the 110 days/yr the expanded trespasser (youth) is on site, he/she is exposed to surface water and sediment 52 of those day. (This is consistent with PVL's request for exposure to surface water being 52 days/yr).
[s]USDA 1985, Report no. 85-1, National Food Consumption Survey, values include a fraction of food produced at home, ie: .35 for fruits and vegetables, .75 for meats and .75 for milk (as recommended in the Exposure Factor Handbook)
[t]EPA 1990, EPA/600/8-89/043, Exposure Factor Handbook, IR for beef and milk are from p. 2- 25-27; IR of drinking water, p. 2-1,9; IR of fish, p.2-33, IR of fruits and vegetables and fraction of time (FI_t) homegrown produce are eaten are from PartII p. 1 -(8-10)
[u]DOE 1992, FEMP Risk Assessment Work Plan Addendum.
[v]Assumes lower frequency and exposure time because Paddys Run is too shallow for swimming and dry during warm months, when such activity would be most likely. Also, assumes that adults and young children will not be playing in Paddys Run.
[w]Assumption, The Superfund Exposure Assessment Manual, April 1988 p. 129, recommends 50 ml/hr for swimming, but Paddys Run is an intermittent stream not deep enough for swimming. Therefore, a slightly lower value of 35 mL/hr seems reasonable.
[x]Based on specific biomedical values provided from the Childrens Hospital at the University of Cincinnati.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

CENTRAL TENDENCY ANALYSIS

SUPPLEMENT NO. 94-007
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000059

Title: Central Tendency Analysis	
SUPPLEMENT NO. 94-007 REVISION NO. 1	7312
Effective Date: March 31, 1994	Page 1 of 3

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
10/11/93	0	Guidance on the preparation of central tendency analysis for remedial investigation risk assessments
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency

1.0 **OBJECTIVE**

The central tendency (CT) is used for comparison of average exposure to the conservative reasonable maximum exposure (RME). A CT analysis will be included in each remedial investigation risk assessment.

2.0 **SUPPLEMENTAL GUIDANCE**

CT exposures will be evaluated for the on-property farmer receptor. All other receptors will be evaluated by the use of RME values.

3.0 **SUPPORTING INFORMATION**

In regards to quantifying exposures, CT evaluations refer to the use of median (50th percentile) human parameters, using the 95th upper confidence limit (UCL) concentration term, as distributed below:

Body Weight	50th percentile
Skin Surface Area	95th percentile*
Intake rates (inhalation, ingestion, etc.	50th percentile
Exposure Frequency	50th percentile
Exposure Duration	50th percentile
Concentration of Contaminant	95th UCL

* EPA will confer with the authors of the skin surface area parameters in atempt to resolve this issue. Until guidance is received from EPA to change this to 50th percentile skin surface area, the 95th percentile values will be used.

4.0 **REFERENCES**

None.

P = 7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

RECEPTOR GUIDANCE

SUPPLEMENT NO. 94-008
REVISION NO. 1

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000063

Title: Receptors Guidance	E-7312
SUPPLEMENT NO. 94-008 REVISION NO. 1	
Effective Date: March 31, 1994	Page 1 of 5

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
10/19/93	0	Lists of exposure scenarios and pathways that are to be used in RI/FS Risk Assessments
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency. Inclusion of additional recreational receptors developed for Operable Unit 5

1.0 **OBJECTIVE**

This guidance lists receptors that are to be used in FEMP RI/FS risk assessments.

2.0 **SUPPLEMENTAL GUIDANCE**

The following current and future land use scenarios and receptors are to be used in RI/FS risk assessment:

- Current Land Use with Access Controls
  - visitor (delivery person)
  - trespassing youth
  - off-property farmer
  - off-property resident child
  - groundskeeper

- Current Land Use without Access Controls
  - visitor (delivery person)
  - off-property resident farmer
  - off-property resident child
  - off-property building user
  - off-property user of the Great Miami River
  - off-property user of milk and meat produced on-property

- Future Land Use with Federal Ownership
  - off-property resident farmer
  - off-property resident child
  - expanded trespasser (formally referred to as the recreational receptor)
  - groundskeeper
  - off-property user of the Great Miami River
  - Recreational use of a wildlife reserve (Operable Unit 5 only)
  - Recreational use of a undeveloped neighborhood park (Operable Unit 5 only)
  - Recreation use of a developed park

- Future Land Use without Federal Ownership
  - on-property resident farmer
  - on-property resident child
  - home builder
  - off-property user of the Great Miami River

3.0 SUPPORTING INFORMATION

3.1 Description of Potential Receptors:

- **Visitor (delivery person)** - evaluates exposures from the activity of a regular visitor (who is not covered by the FEMP Health and Safety Program) to an operable unit. Exposure routes include: direct radiation and inhalation of particulates, volatiles, and radon.

- **Trespassing Youth** - describes someone, ages 7 to 18 years, trespassing on an operable unit. Possible exposure routes include: inhalation of particulates, volatiles, and radon; incidental ingestion of soil/sediment and surface water (if it exists within that operable unit); direct radiation; and dermal contact with surface water and surface soils.

- **Off-property resident farmer** - evaluates a farm family living adjacent to the FEMP property. Exposure routes include: inhalation of particulates, volatiles, and radon; ingestion of groundwater and home grown fruits, vegetables, meat and milk; dermal contact while bathing; and inhalation of volatiles from household use of groundwater. Groundwater pathways (including perched water) will be evaluated by Operable Unit 5. Operable Unit 4 evaluated direct radiation exposure at the property line nearest the K-65 silos.

- **Off-property resident child** - the child, ages 0 to 6 years, is evaluated separately from the adult farmer because it is the critical receptor. The child will be exposed through the same pathways as the farmer.

- **Groundskeeper** - evaluates a full-time employee who maintains fences, cuts grass, and performs general security.

- **On-property building user** - if the operable unit under evaluation contains structures which can be habitated or salvaged, this receptor may be applicable. Pathways that could be included are: incidental ingestion of soils; inhalation of particulates, volatiles, and radon; direct radiation; dermal contact with soils; and ingestion of animal products from animals grazing on site.

- **User of the Great Miami River** - evaluates use of the river for recreational, household, and agricultural uses. This receptor could be evaluated under either a future or current land use. Pathways include ingestion of water, dermal contact with water sediment, ingestion of fish and agricultural products, and inhalation of released volatiles.

- **Off-property user of meat and milk produced on site** - evaluates a particular use pattern - the consumption of meat and milk from livestock that may graze on FEMP property (i.e., in the South Field).

- **Expanded Trespasser (formerly the Recreational User)** - examines exposure to individuals who trespass on site and use the site for recreational activities. Exposure pathways include: inhalation of particulates, volatiles, and radon

incidental ingestion of soils and surface water; dermal contact with soils and surface water; and direct radiation.

- **On-property resident farmer** - assumes a farm family would reside on the FEMP property and produce much of their own food. Pathways would include: inhalation of particulates, volatiles, radionuclides, and indoor concentration of radon; ingestion of soil/sediments, groundwater, homegrown fruits, vegetable, meat and milk; dermal contact with soils and groundwater; and inhalation of volatiles released from use of groundwater.

- **On-property resident child** - assumes a child, age 0 to 6 years, is exposed to the same pathways as the adult farmer.

- **Construction (Home builder)** - evaluates a construction worker digging a basement and constructing a building. This receptor would be exposed to deeper soils than the other receptors. Pathways include: inhalation of particulates, volatiles and radon; dermal exposure to soils; incidental ingestion of soil; and direct radiation. The pathways examined under this scenario may also be evaluated under the on-property farmer scenario. In such a case, it would be assumed that the farmer constructed his own home and this receptor would be unnecessary.

3.2 Additional Recreational Receptors Developed for Operable Unit 5

- **Recreational User of a Wild Life Reserve** - evaluates risk to humans from release of all or portions of the site for a wild life reserve. Activities include hiking, bird watching, viewing wild life, and jogging. The intent of this land use is to minimize disturbance for wild life. Pathways examined are inhalation of particulates and gases, external radiation, incidental ingestion, and dermal contact with soil.

- **Recreational User of a Neighborhood Park with Limited Facilities** - Under this scenario, there would be no rest room facilities or developed recreational facilities with the exception of walking trails and open spaces of grassy fields. Activities and exposure pathways would be the same as those examined for the wild life reserve, except this park would allow for ball playing, picnicking, and dirt bike riding.

- **Recreational User of a Neighborhood Park with Developed Recreational Facilities** - This park encourages longer exposure time because there are rest rooms and developed recreational facilities, which would allow for more activity. Exposure pathways are the same as those listed for the other recreational scenarios.

4.0 REFERENCES

None.

7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

PRELIMINARY REMEDIATION GOALS/ PROPOSED REMEDIAL LEVELS DEVELOPMENT

SUPPLEMENT NO. 94-009
REVISION NO. 2

OCTOBER 5, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000069

Title: Preliminary Remediation Goals/Proposed Remediation Levels Development	
SUPPLEMENT NO. 94-009 REVISION NO. 2	7312
Effective Date: October 5, 1994	Page 1 of 8

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
02/10/94	0	Provides requirements for the methods to be used for developing preliminary remediation goals and proposed remedial levels
03/31/94	1	Change for submittal to U.S. Environmental Protection Agency
10/05/94	2	Change to incorporate Agency comments and operable unit directives

1.0 OBJECTIVE

Corrective or remedial actions at Superfund sites are planned and conducted to ensure protection of human health and the environment from residual levels of contaminants remaining after remedial actions have been completed. In order to accomplish this goal, consistent and defendable methods must be developed and employed that consider risk to human health as a criterion when establishing cleanup levels and implementing remedial actions.

As required by the Amended Consent Agreement, a baseline risk assessment is performed as an integral part of the Remedial Investigation (RI) report submitted for each operable unit at the Fernald Environmental Management Project (FEMP). The baseline risk assessment provides a detailed estimate of potential current and future human health impacts by evaluating levels of both naturally occurring and anthropogenic (manmade) contaminants. This is accomplished by examining existing analytical data from sampled environmental media including surface soils, subsurface soils, groundwater, surface water, and sediments. Stored waste or construction material may also be assessed depending on the defined responsibilities of the operable unit in question.

Preliminary remediation goals (PRGs) are developed based on the following information:

- Constituents detected in sampling and analysis of media
- Constituents of potential concern (CPCs) and contaminants of concern (COCs) that remain after screening {reference Supplemental Guidance to the Risk Assessment Work Plan Addendum [RAWPA] No. 94-002 (DOE 1994)}
- Applicable or relevant and appropriate requirements (ARARs)
- Proposed future land use
- Relevant exposure pathways
- Toxicity information
- Target risk levels

2.0 The PRG Development Process

The following steps describe the process in which PRGs are developed and modified to eventually become final remediation levels (FRLs). Figure 1 depicts this PRG/FRL development process in the form of a logic diagram.

STEP 1

2.1 Use of Risk Assessment Guidance for Superfund (RAGS) Part B Screening PRGs (Pre-RI)

In the pre-RI or scoping phase of the PRG/PRL development process, the operable unit-specific or other relevant data is reviewed and a list of detected constituents is assembled. As part of the CPC selection process2, screening PRGs are calculated from RAGS Part B (EPA 1991), based on an incremental lifetime cancer risk (ILCR) level of

10^{-7} or a hazard index (HI) of 0.1. These screening PRGs are calculated utilizing equations that appear in RAGS representing residential land use for each detected chemical which exceeds its upper confidence level (UCL) background concentrations in sampled media. These concentrations (i.e., screening PRGs) are used to screen out CPCs from the data set. It is important to note that these screening PRGs are used only as part of the toxicity screening procedure for CPC selection and not for the development of final cleanup levels.

This list of constituents is then subjected to additional procedural screening protocol which addresses macronutrients, micronutrients, ubiquitous compounds, detection frequency, and other considerations as described in the Supplemental Guidance to the RAWPA No. 94-003.

STEP 2

2.2 Site-Specific Risk-Based Preliminary Remedial Goals (RI)

Computation of media-specific, COC-specific risks is presented and summarized in the baseline risk assessment. By definition, these calculated risks represent total potential risks experienced by defined hypothetical receptor(s) from direct exposures to individual media (groundwater, surface water, soil, and sediment). The receptors and exposure pathways are selected based upon both current and potential future land use of the site and the surrounding area. This calculated risk includes contributions from background levels of COCs, if relevant.

In preparation of the risk assessment appendix of the RI report, background risks and risk-based PRGs are calculated and presented simultaneously with total calculated risks to evaluated receptors.

Site-specific risk-based PRGs are defined for the purposes of a baseline risk assessment to comply with guidance provided in Part B of RAGS as follows:

- COC-Specific
  A risk-based PRG is calculated for each COC selected as a result of the screening process that takes place in the RI baseline risk assessment (Supplemental Guidance to the RAWPA No. 94-002).

- Media-Specific
  A risk-based PRG is calculated for every COC in each media type that can act as a potential exposure source to the receptors undergoing evaluation. No potential cross-media impacts are evaluated at this time.

- Incrementally Risk-Based
  Risk-based PRGs are calculated at ILCR target risk levels of at the 10^{-6}, 10^{-5}, and 10^{-4} [National Priorities List (NPL), 40 Code of Federal Regulations (CFR) 300] for the appropriate hypothetical receptors and exposure scenarios evaluated for the site. The 10^{-6} risk level is considered the "point of departure." For chemical toxicants, a hazard quotient (HQ) value of 0.2, based on reference doses (RfDs) obtained from the Health Effects Assessment Summary Tables [HEAST (EPA 1992b)], is used for risk-based PRG development.

- ARARs
  All ARARs and to be considered (TBC) regulations regarding maximum contaminant levels (MCLs) are applied to the PRG development process. If ecological impacts are to be incorporated, as they will be in Operable Unit 5, benchmark criteria will also be considered. These ARARs are presented in a table with the risk-based PRGs in the baseline risk assessment for purposes of comparison and as references for use in the feasibility study (FS) process.

The models and parameters used for generating the site-specific PRGs are provided in the RAWPA and the Supplemental Guidance to the RAWPA unless otherwise specified. Also, detailed discussions of these values and the specific methods used for calculating PRGs are addressed in each operable unit RI baseline risk assessment.

If risk to either the current or future reasonable maximum exposure (RME) receptor exceeds the 10^{-6} to 10^{-4} risk range, risk managers and regulators will determine if remedial action is warranted and a FS report is necessary.

STEP 3

2.3 Modified Preliminary Remediation Goals - (FS)

The site-specific PRGs established in the RI baseline risk assessment are subsequently imported into the FS. The purpose of the RI report is to determine the nature and extent of contamination that falls within a defined operable unit and to determine baseline risks to specified receptors posed by this contamination. The purpose of the FS process is to identify the safest, most efficient, and lowest cost remedy that will bring residual risks to human health and the environment to levels considered acceptable by the regulatory agencies.

Calculated site-specific risk levels to key hypothetical receptors are a crucial parameter in the FS decision-making process. Risk-based, site-specific PRGs are derived from receptor exposure assumptions determined in the baseline risk assessment and are used as a major factor for comparing remedial alternatives undergoing evaluation. In the FS, site-specific PRG values developed in the RI baseline risk assessment are usually adjusted by applying modifying factors. Modifying factors can be divided into several domains which include:

- ARARs
  ARARs presented in the baseline risk assessment are now evaluated in comparison to site-specific PRGs. The concentrations considered most protective to human health and the environment (the lowest concentrations) are generally retained.

STEP 4

- Cross-Media Impacts
  Cross-media impacts refer to the potential for one contaminated media type to impact another. Most generally, it refers to the potential for contaminated soil and sediment to impact groundwater and surface water. Cross-media impacts assessed as a result of fate and transport modeling are taken into consideration for each site-specific PRG (risk-based or HI-based) and ARAR. The resulting threshold concentrations determined to be protective of other media are sometimes referred to as cross-media preliminary remediation goals (cPRGs). If an ARAR or

risk-based PRG is already protective against cross media contamination, the cPRG will not modify the original value. If the cPRG or ARAR value is lower than the risk-based counterpart, it will supersede the risk-based PRG.

As described above, the risk-based, site-specific PRGs developed in the RI are compared with ARARs and the lowest values are retained. Those values are further compared with cPRGs within the media type. For example, an ARAR may be retained for a constituent in soil because its value is lower than the site-specific PRG (both risk-based or HI-based) for that constituent. Due to the modeled cross-media impacts, that value may not be protective of an ARAR (MCL) for that same constituent in groundwater. In such a case, the risk-based PRG/ARAR for that constituent in groundwater would be modeled to derive a more stringent cPRG for soil. The PRGs resulting from this process of comparison and replacement are then retained as "modified PRGs."

STEP 5

- Engineering Controls
  Information regarding proposed disposal cell or consolidation area specifications, site subsurface geology, meteorological information, and volume and contaminant concentration estimates from preliminary remedial design are required by modelers to assist in development of waste acceptance criteria (WAC). The WAC will specify the maximum contaminant levels that can be stored in the disposal cell or consolidation area and still remain protective from groundwater impacts for a specified period. Final decisions regarding disposal cell/consolidation area details and accompanying WAC(s) will be presented in the ROD.

STEP 6

2.4 Preliminary Remedial Action Levels (PRALs) - (FS)

The PRAL is defined as a modified PRG that considers the media-specific background concentration of the COC at the location in question.

There is a global assumption that those conducting cleanups are not responsible for eliminating risk posed by levels of naturally occurring constituents present in the considered media. This is pertinent mainly to naturally occurring radionuclides and carcinogenic metals that are present in most soils, sediments, and to a lesser extent groundwater. In order to preclude unacceptable risk levels in residuals due to the presence of an abnormally high background component(s), background levels and risks of naturally occurring constituents will be presented and "considered" for addition to the modified PRG(s) representing the "acceptable risk level". With this information, risk managers, regulators, and other decision makers can consider the proposed cleanup level for each COC in question and suggest modifications to the cleanup level(s) if deemed necessary.

STEP 7

2.5 Proposed Remediation Levels -(Proposed Plan)

Proposed Remediation Levels (PRLs) are defined as the cleanup levels of the COCs on a media-by-media basis that have been incorporated into the Proposed Plan (PP) for each

operable unit. At this point, background levels of the relevant COCs have been reviewed and an approach to establishing FS PRLs has been established.

STEP 8

2.6 Final Remedial Levels (Record of Decision)

FRLs are defined as PRLs that have been reviewed, have received concurrence by the regulatory agencies, and are submitted as viable cleanup levels for remediation. These FRLs are published in an operable unit-specific record of decision (ROD). FRLs will only be confirmed after residual risks have been evaluated and the contributions of the operable unit under consideration have been incorporated into overall site risks. It may be necessary to review and perhaps revise the FRLs of individual operable units in the context of site-wide integration. A major factor in balancing this sitewide "risk budget" will be determination of the most cost effective reductions to contaminant source terms. This can only be finalized after all media-specific contaminant sources present in the individual operable units have been quantified and risks to evaluated receptors have been calculated.

STEP 9

2.7 Remedial Design/Remedial Action (RD/RA)

FRL values are used in the RD/RA process to determine volumes of media that must be removed in order to meet requirements to be "protective of human health and the environment." As remediation is conducted, more data will be generated than was available during the PRG/FRL development process. An increase of valid data points will diminish the degree of uncertainty present when calculating representative concentrations in media. This additional information may result in modifications to the original design specifications, while remaining in compliance with the established FRLs.

3.0 SUPPORTING INFORMATION

None

4.0 REFERENCES

U.S. Department of Energy, 1993, "Site-Wide Characterization Report, Fernald Environmental Management Project, Fernald, OH, Remedial Investigation and Feasibility Study, Final," U.S. Department of Energy, Fernald Field Office, Fernald, OH.

U.S. Department of Energy, 1994, "Supplemental Guidance to the Risk Assessment Work Plan Addendum, Fernald Environmental Management Project, Fernald, OH," U.S. Department of Energy, Fernald Field Office, Fernald Ohio.

U.S. Environmental Protection Agency, 1992a, "Integrated Risk Information System (IRIS)", on-line date service, U.S. EPA, Washington, DC.

U.S. Environmental Protection Agency, 1992b, "Health Effects Assessment Summary Tables, Annual Update FY 1992, including Supplement A, July 1992," OERR 9200.6-303 (92-1), U.S. EPA, Office of Emergency and Remedial Response, Washington, DC.

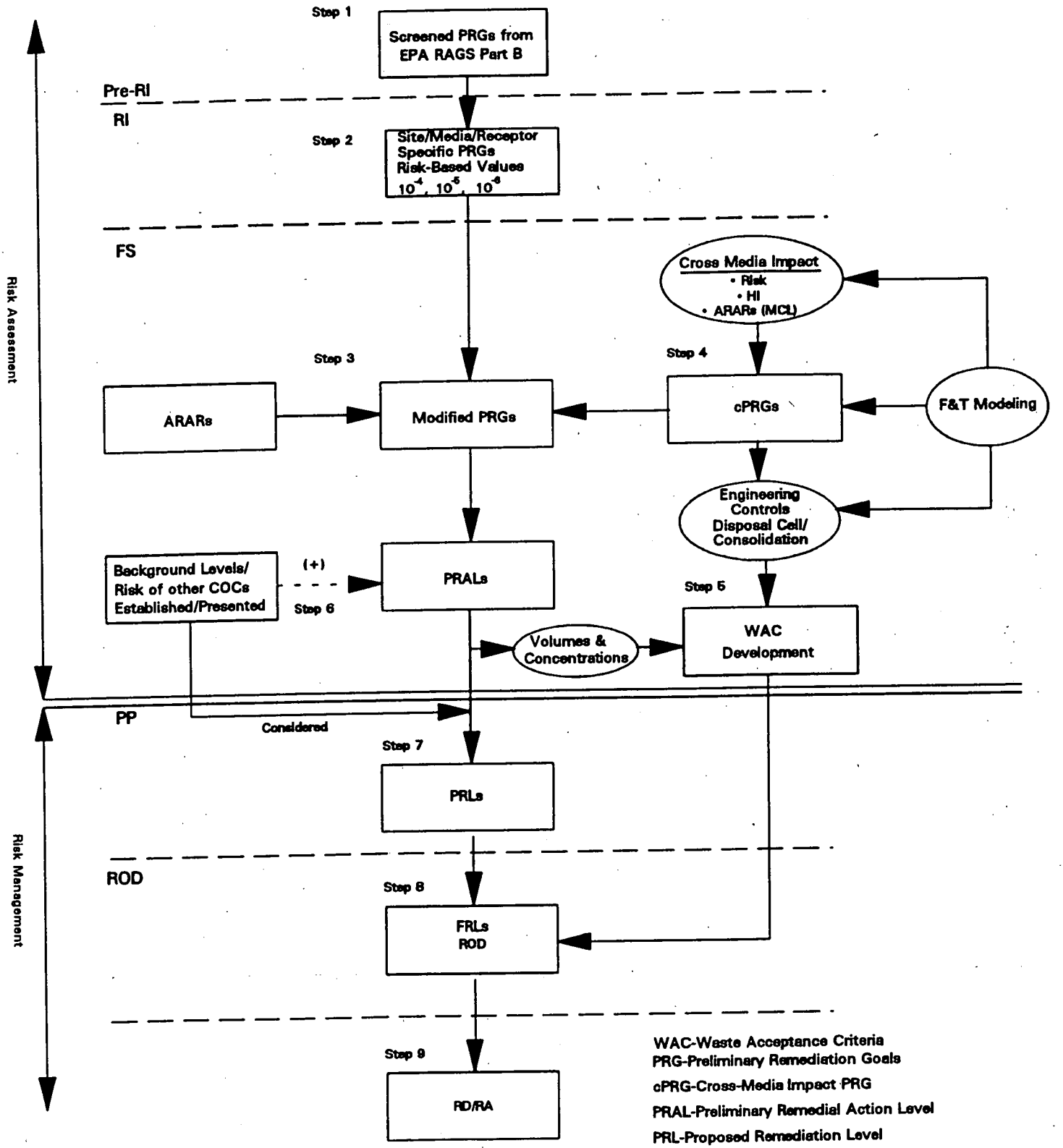
U.S. Environmental Protection Agency, 1989, "Environmental Protection Agency National Primary Drinking Water Regulations," 40 CFR 141, as amended by 54 FR 27526, June 29,

1989 and 54 FR 30001, July 17, 1989, The Bureau of National Affairs, Inc., Washington, DC.

U.S. Environmental Protection Agency, 1988, "Federal Guidance Report No. 11," U.S. EPA, Washington, DC.

U.S. Environmental Protection Agency, 1991, "Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Manual, Part B, Development of Risk-Based Preliminary Remediation Goals, Interim," OSWER Directive 9285.7-01B, EPA, Office of Emergency and Remedial Response, Washington, DC.

FIGURE 1



WAC-Waste Acceptance Criteria
PRG-Preliminary Remediation Goals
cPRG-Cross-Media Impact PRG
PRAL-Preliminary Remedial Action Level
PRL-Proposed Remediation Level
FRL-Final Remediation Level

E - 7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

CHILD'S VENTILATION RATES

SUPPLEMENT NO. 94-010
REVISION NO. 0

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000079

Title: Child's Ventilation Rates	F-17312
SUPPLEMENT NO. 94-010 REVISION NO. 0	
Effective Date: March 31, 1994	Page 1 of 4

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
03/31/94	0	Provides U.S. Environmental Protection Agency's published exposure factors for the child's inhalation rate.

1.0 **OBJECTIVE**

The ventilation volumes and rates described within this supplement conservatively approximate those of the normal active child. The value developed for risk assessments is an upward adjustment of the normal child to the moderately active child whose ventilation rate and volume are on the high side of the normal range.

2.0 **SUPPLEMENTAL GUIDANCE**

The calculated value of 0.5 cubic meters (m^3) per hour is the appropriate value for the child's inhalation rate and should be used in FEMP risk assessments. The value of 0.5 m^3 per hour is recommended as the reasonable inhalation rate for children 0 to 6 years of age and accounts for an increased activity above the normal resting activity level. This value is justified by the physiological parameters currently used by pediatric physicians from the Children's Hospital at the University of Cincinnati Medical Center.

3.0 **SUPPORTING INFORMATION**

The U.S. Environmental Protection Agency's (EPA) published exposure factors should be used **unless alternate or site specific values** can be justified by supporting data.

The rate at which oxygen, which becomes partially depleted during increased activity levels, resaturates circulating hemoglobin will determine human ventilatory rates and volumes. For a healthy active child, oxygen resaturation of hemoglobin occurs within a few minutes at a ventilation rate appropriate to the body size. The autonomic nervous system controls the ventilatory rate; the ventilation rate automatically decreases as hemoglobin is resaturated with oxygen. Continued hyperventilation at an hourly rate beyond a few minutes duration is unlikely and will cause a person to pass out.

Recommendations for ventilatory rates, developed in consultation with Dr. Robert Wilmont, Director of Pulmonary Medicine, and Dr. Frederick Ryckman, Pediatric Surgeon, both practitioners at the Children's Hospital at the University of Cincinnati Medical Center, indicated the range of ventilation volume for children between birth and six years of age is 15 to 20 cubic centimeters (cm^3) per breath per kilogram (kg) of body weight.

The range of ventilation rates with respect to children 0 to 6 years of age are:

- 20 to 30 breaths per minute for an infant (birth to 2 years of age)
- 15 to 20 breaths per minute for a small child (3 to 4 years of age)
- 12 to 15 breaths per minute for an older child (5 to 6 years of age)

Using conservative weight values of 10 kg for an infant, 15 kg for a small child, and 20 kg for an older child, ventilation volumes per breath according to body weight are calculated as follows:

- 10 kg x 15 to 20 cm^3 per breath per kg equals 150 to 200 cm^3 per breath
- 15 kg x 15 to 20 cm^3 per breath per kg equals 225 to 300 cm^3 per breath
- 20 kg x 15 to 20 cm^3 per breath per kg equals 300 to 400 cm^3 per breath

Multiplying the ventilation rates (breaths per minute) by the ventilation volumes (cm^3

per breath) for each age group produces the following range of ventilatory volumes per minute (cm^3 per minute):

- 3.0 to 4.0 liters per minute (low) and 4.5 to 6.0 liters per minute (high) for an infant weighing 10 kg
- 3.3 to 4.5 liters per minute (low) and 4.5 to 6.0 liters per minute (high) for a child weighing 15 kg
- 3.6 to 4.8 liters per minute (low) and 4.5 to 6.0 liters per minute (high) for a child weighing 20 kg

The higher ventilatory volumes per minute for children 0 to 6 years of age are identical. We assume that 4.5 liters per minute is a conservative high (but not the highest) value for normal active children 0 to 6 years of age. An activity factor of 2.1 is introduced into the calculated rate to account for a moderately active child and to assure conservatism in the risk assessment process. Thus, at a rate of 4.5 liters per minute, this moderately active child 0 to 6 years of age is breathing at a rate of 0.57 m^3 per hour (4.5 liters per minute x 60 minutes per hour x 2.1 equals 567 liters per hour). This value can be used as a higher than average value and covers the range of breathing rates during moderately active daily movements.

Realistically, in spite of the increased activity, children could not continue to breath at a maximum value (hyperventilation) for more than several minutes (to do so would cause the child to pass out). However, they are assumed to be moderately active, thus, the higher ventilation rate.

Therefore, using the higher ventilation rate and the moderate activity factor for an active child who will ventilate, but not continuously, at a higher rate, the ventilatory rate of 0.5 m^3 per hour is reasonable and appropriate for children between 0 to 6 years of age. This value is realistic and conservative and is based upon physiological parameters established and currently used within the greater Cincinnati medical community.

4.0 REFERENCES

U.S. Environmental Protection Agency, March 1990, "Exposure Factor Handbook, Part II," U.S. EPA, Washington, DC.

F-7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

DERMAL SLOPE FACTORS FOR POLYCYCLIC AROMATIC HYDROCARBONS OR OTHER CONTAMINANTS OF CONCERN

SUPPLEMENT NO. 94-011
REVISION NO. 0

March 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000084

Title: Dermal Slope Factors for Polycyclic Aromatic Hydrocarbons or other Contaminants of Concern	
SUPPLEMENT NO. 94-011 REVISION NO. 0	7312
Effective Date: March 31, 1994	Page 1 of 5

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Title: Dermal Slope Factors for Polycyclic Aromatic Hydrocarbons or other Contaminants of Concern	
SUPPLEMENT NO. 94-011 REVISION NO. 0	7312
Effective Date: March 31, 1994	Page 2 of 5

RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
03/03/94	0	Provides guidance to seek out dermal factors when unavailable in IRIS, HEAST, or ECAO documentation.

1.0 **OBJECTIVE**

An U.S. Environmental Protection Agency (EPA) comment (quoted below) describes the inappropriate extrapolation of dermal cancer slope factors from oral slope factor values for polycyclic aromatic hydrocarbons (PAHs). Additionally, the dermal toxicity information is not properly considered in the risk analysis nor is it presented in the Remedial Investigation (RI) report.

> "Dermal absorption of PAH's in this manner (using oral slope factors) will not be protective, **and dermal toxicity values should not be derived for these compounds."** EPA, August 10, 1993

Dermal slope factors were unavailable from EPA's recommended documents including Integrated Risk Information System (IRIS), Health Effects Assessment Summary Tables (HEAST), and Environmental Criteria and Assessment Office (ECAO) documents. Extrapolation of cancer slope factors from other routes of exposure is inappropriate due to varied absorption, metabolic transformations, and target organ end point responses. In the Operable Unit 4 RI report, the risk assessors extrapolated dermal risk slope factors from oral values in an attempt to quantify the possible contribution to the site risk from the dermal path of PAH exposure. The risk assessors misread the EPA comment to mean that those values should be completely removed from the RI. They removed the values; however, they failed to provide alternative qualitative information of the possible impact on risk from that path due to PAHs. Therefore, the following policy guidance is provided.

2.0 **SUPPLEMENTAL GUIDANCE**

When slope factor information is unavailable from IRIS, HEAST, or ECAO for dermal PAHs or any other chemical, the risk assessor is required to conduct a separate search for dermal toxicity information. The first step is to seek out any information published by the Agency for Toxic Substances Disease Registry (ATSDR). If unavailable, the risk assessor must conduct an independent review of the toxicology, epidemiology, and pathology literature.

3.0 **SUPPORTING INFORMATION**

Start the search by identifying information on the toxicity of the chemical in question. Conduct a critical examination of the information. Identify the quality of the study. Determine the suitability of the experimental animal, tissue, cells, or biochemical process in relation to the author's question(s). Also, determine the appropriateness of the experimental protocol or methodology used to answer the author's question(s). Describe how this methodology and evidence supports the conclusion(s).

In the RI report text, determine and describe any health effects and the extent to which the contaminant of concern (COC) can impact the risk. Describe and reference the information found and qualitatively explain the effects of exposure to the COC and how that pathway may impact risk. Describe the route of exposure, the dose, target organ, response time, and any sensitivities of the animal. Describe the target organ tissue and end point associated with this exposure pathway. Correlate potency of this chemical and how it may contribute to the risk from this pathway. Provide a qualitative discussion of the possible impact of this exposure path to the total risk,

correlating the possible effects on human response. Finally, provide a discussion on the amount and type of uncertainty of this relationship on risk in the uncertainty section of the RI report.

For PAHs:
When presenting risk information on the B2 (probable human carcinogen) PAHs, the RI report should provide risk information of available oral and/or inhalation slope factors. For dermal exposure, provide a discussion of the toxicity as above. **The proper input into text should be "the contribution to cancer risk from dermal exposure to PAHs indicates that path to be at least as toxic as the oral route."** Therefore, once you have calculated the oral risk, double it (i.e., 2 X 1.0 x 10^{-6} = 2.0 x 10^{-6}) to account for the impact or contribution from the dermal route of exposure. Also, when calculating the preliminary remediation goal, this value will be halved.

Concurrently, it is important to prepare an evaluation of the risks using the following relative potency values.

Compound	Relative Potency
Benzo(a)pyrene	1.0
Benz(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenz(a,h)anthracene	1.0
Indeno(1,2,3-c,d)pyrene	0.1

The data indicate that Benzo(a)pyrene (BaP) is the index toxin among the group of PAHs; Dibenz(a,h)anthracene is equally as potent. However, all PAHs are referenced with BaP. Since carcinogenic capabilities among PAHs vary across routes of exposure, describe the relationship of exposure concentrations and the potency. The uncertainty accompanying these descriptions must be addressed in the uncertainty section of text.

A decision matrix is available in EPA guidance to identify whether dermal exposure requires assessment. It is described below to determine the importance of dermal exposure during risk analysis. (EPA, Dermal Exposure Assessment: Principles and Application, page 9-2).

1. Will dermal contact occur in the scenario?
   a. No-do not consider further.
   b. Yes-review dermal toxicology and determine if chemical causes skin effects.

2. Is the contaminant in water/soil that is dermally contacted also be consumed?

a. No-conduct detailed assessment of water/soil exposure and consider possible contribution from dermal exposure.
b. Yes-critically examine water/soil exposure.

3. Is water Kp greater than 10^{-1} centimeters per hour or is absorption from skin greater than 10 percent?
   a. No-dermal analysis may not be necessary.
   b. Yes-conduct a detailed risk analysis and evaluate any possible contribution from dermal exposure.

4.0 REFERENCES

U.S. Environmental Protection Agency, 1993a, "Health Effects Assessment Summary Tables, FY-1991," OERR 9200.6-303(91-1), EPA, Washington, DC.

U.S. Environmental Protection Agency, 1993b, "Integrated Risk Information System (IRIS)," Computer database, EPA, Washington, DC.

U.S. Environmental Protection Agency, 1992, "Dermal Exposure Assessment: Principles and Applications," EPA/600/8-91/011B, Exposure Assessment Group, Office of Health and Environmental Assessment, U.S. EPA, Washington, DC.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

HUMAN SURFACE AREA AND FOR DERMAL CONTACT WITH SOILS

SUPPLEMENT NO. 94-012
REVISION NO. 0

MARCH 31, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000090

Title: Human Surface Area for Dermal Contact with Soils	
SUPPLEMENT NO. 94-012 REVISION NO. 0	7312
Effective Date: March 31, 1994	Page 1 of 6

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
03/31/94	0	Provides the physiological parameter to be used for the human body surface area during calculation of dermal exposure

1.0 OBJECTIVE

A comment .S. Environmental Protection Agency (EPA) consisted of the upper bound [2.3 square meters (m^2)] body surface area parameter. The comment is quoted below:

> **"Regarding surface area (SA) parameter values for the dermal contact with soil/sediments pathways. Please reread the OSWER Directive, 9285.6-03. The directive specifies that the upper-bound values should be used for IR (intake/contact rate). It goes on to say.."the body surface area is a measure of contact rate (contact area) in the dermal equations. Therefore, it is appropriate to use upper bound values (95th percentile values) as indicated in the dermal guidance." Pat Van Leeuwen, October 27, 1993.**

2.0 SUPPLEMENTAL GUIDANCE

The 95th percentile body surface area value of $2.3m^2$, described by EPA, is the physiological parameter to be used for the human body surface area during calculation of dermal exposures for all risk assessments. The Fernald Environmental Management Project (FEMP) feels that this guidance is inappropriate and has presented a dissenting opinion. The matter will be examined by EPA headquarters; until EPA acts upon this matter, the above value will be used. The support for the dissenting opinion is discussed below.

3.0 SUPPORTING INFORMATION

The FEMP's evaluation of EPA guidance and established human surface area parameters suggests that the dermal guidance is incorrect when applied to an average body weight reference man. The surface area is highly correlated with body weight and height. To alter this relation is inappropriate and suggests the average 70 kilogram reference man has the body surface area of a 100 kilogram or greater person. This relationship extends outside physiological reality.

It is further suggested that the values are inappropriate when examined in light of EPA's own supporting data for such guidance (Exposure Factors HAssessment, EPA600/8-89/043, Chapter 4 and Appendix 4A). The guidance cites several references and provides equations ($SA=K*B.Wt^{2/3}$ and $SA=Ao*Ht^{a1}*Wt^{a2}$) identifying the high degree of correlation between body weight, body height, and body surface area, and uses that relation extensively. Due to the EPA indicating that the physiological parameters are highly correlated, any other use would be incorrect and in conflict with this philosophy.

The above EPA comment suggests that contact rate and contact area are equivalent; that is incorrect. Risk Assessment Guidance for Superfund (RAGS), Section 6, page 6.2 supports the fact that contact rate and contact area are not the same. The EPA cited definition for contact rate is a measure of the amount of medium (liters of water ingested per day or mg/cm^2-day soil contacted) per unit time. The definition for contact area is the body surface area available for contact with contaminated medium (in m^2).

RAGS, Section 6.4, page 6-19 states that, "the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be individual maximum values but in combination with other variables will result in estimates of RME (reasonable maximum exposure).

Determination of "reasonable" cannot be based solely on quantitative information but requires the use of professional judgement." The maximum body surface area used with an average body weight and average lifetime exposure is inconsistent with professional toxicological judgement.

OSWER directive 9285.6-03, Supplemental Guidance, Standard Default Exposure Factors, Interim Final, March 25, 1991, page 1 states that "**exposure factors** (not physiological parameters) in the document should be used unless alternate or site specific values can be justified by supporting data."

The FEMP's review of the OSWER directive concludes that guidance does not clearly establish using the upper bound surface area with the average body weight and average lifetime. Text on page 2 states:

> "The goal of the RME estimates for each scenario at each site is to combine the upper bound and mid-range **exposure factors** as in the following equation.
>
> Intake = (C x IR x Ef x ED)/(BW x AT)

where:

C	=	**Concentration of chemical in medium of concern**
IR	=	**Intake/contact rate (upper bound value)**
EF	=	**Exposure frequency (upper bound value)**
ED	=	**Exposure duration (upper bound value)**
BW	=	Body weight (average value)
AT	=	Averaging time (exposure duration in days for non- carcinogens and a 70 year lifetime for carcinogens)."

Contact rate is the concentration of a chemical contaminant in contact with a body surface area per unit time or event. This is an exposure rate and is denoted by mg/m^2/unit time period. Based upon EPA's definitions above, the contact rate is an **exposure parameter** and should be the upper bound (RME). However, the body surface area exposed is a physiological parameter that should be an average and is consistent with the average body weight and the average lifetime value (for cancer calculations). There are several reasons for this relationship.

In the above equation, the exposure parameters are upper bound while the physiological parameters, body weight, and averaging time are clearly average (central tendency) values. It is appropriate that the body surface area of a human physiological parameter should also be the average (central tendency) value.

Federal Register, Vol 57, No 104, Friday, May 29, 1992, page 22895 recommends using dose estimates that can be compared with the available dose-response data. It also describes use of an average dose rate [average dose (mg) of chemical per unit time] for a time period as a useful number for risk assessment. It also states the **average surface area** should be used in calculating the uptake dose via dermal exposure (page 22896, Section 2.1.4.2).

Dermal Exposures HAssessment, January 1992, pages 8-9 describe the equations used to

develop surface area. Section 8.4 includes discussions by several authors (most notably Gehan) to support EPA's position that skin surface area is a highly correlated function of body weight and height. Since the average person's surface area is a closely correlated function of body weight and height, any relationship of the dermal exposure to the surface area must be correlated with average body weight (70 kilograms). To use 70 kilograms in the dermal equation with a RME surface area is scientifically and medically inappropriate. Risk calculations using an average person's body weight with an RME surface area present a significant bias and is scientifically indefensible (L.J. Phillips, R.J. Fares, and L.G. Schweer, 1993, "Distributions of Total Skin Surface Area to Body Weight Ratios for use in Dermal Exposure Assessments," Journal of Exposure Analysis and Environmental Epidemiology, Vol. 3: 331-338).

Dermal Exposures HAssessment, Part 2, Application of The Dermal Exposure Assessment identifies the human body surface areas to range from 17,000 to 23,000 square centimeters (cm^2). The mean value is 20,000 cm^2 (2.0m^2). Thus, an appropriate mean surface area that should be used for the reference man is 2.0m^2.

Dermal Exposures HAssessment, Chapter 9.1, page 9-1 is the example used for EPA's decision matrix regarding the importance of dermal uptake and uses an exposed surface area of 20,000 cm^2 or 2.0m^2.

Dermal Exposures HAssessment, Table 8-6 is an example where the table headings for central tendency (mean) surface areas is 20,000 cm^2 and the RME value for surface area is 23,000 cm^2. In both examples, the situations reflect the use of central tendency values of surface area with the central tendency event time, frequency, and duration (see Table 8-6, page 8-20).

Dermal Exposures HAssessment, page 9-18 compares the amount of dose received by the average adult via dermal uptake and ingestion, and the equation example uses the average skin surface area of 20,000 cm^2.

An additional consideration is the use of data from the Environmental Criteria and Assessment Office (ECAO) for dermal uptake from soil. The use of an upper limit value for ABS with two central tendency values AF and SA results in an overall DA_{event} that is above the average. If the upper bound for AF and SA are also used, then the DA_{event} would result in a 99.78th percentile value. This is clearly outside a reasonable approach as directed by RAGS. (D.E. Burmaster and R.E. Harris, 1993, "The Magnitude of Compounding Risks in Superfund Assessments", Risk Analysis, Vol 13: 131-34).

In Section 4 of the Exposure Factors HAssessment, Skin Surface Area, EPA uses regression equations to correlate height and weight to establish surface areas. This also describes the use of surface area in relation to the height and body weight. Nowhere do any of the references or examples explicitly state that the upper bound SA should be used with normal body weight and average lifetime. (EPA citation, Gehan, George, 1970, "Estimation of Human Body Surface Area from Height and Weight," Cancer Chemotherapy Reports, Vol. 54 No.4: 225-235).

However, EPA guidance on using average body surface area in the exposure assessment

equation is found in the Federal Register, Vol. 57, No. 104, Section 2.1.4.2. This section deals with the dermal route of uptake and each of the equations, 2.8, 2.9, and 2.10, describes the average daily dose calculations using the average body surface

The guidance from RAGS (page 6-41, et seq., Exhibit 6-15, et seq.) states "for dermal contact with chemicals in soil, use 95th or 90th percentiles for **contact rate and exposure frequency variables** and the **50th percentile for total body surface area (1.94/2.0 M^2) for (SA)."**

Based upon the above, EPA philosophy and published documents are consistent in their philosophy that mean surface area should be used with mean body weight when used in risk assessments. Thus, a 1.94 or 2.0m^2 (19,400 to 20,000cm^2) central tendency physiological parameter value should be used with mean physiological parameters; however, exposure parameters should be at the reasonable maximum value (RME).

Based upon the review of philosophy espoused in EPA documents, a realistic approach to evaluating the dermal risk would be to prepare two sets of calculations, one using 50th percentile exposure doses with the 50th percentile physiological parameters and a second set of calculations using 90th/95th percentile RME exposure parameters with the mean physiological parameters. These risk values will provide a realistic yet conservative range of risks and indicate probable mean risk and the reasonable maxi risk accompanying the average and maximum worst case exposure scenarios. combination allows for realistic decision making.

The foundation of toxicology indicates that dose and duration are the most important factors when discerning toxicity. The risk values identify the possible adverse effects associated with a dose rate (milligram chemical/per kilogram body weight) and duration of exposure. This dose rate can reasonably be an average (CT) rate or for greater conservatism, the dose rate can be the reasonable maximum exposure (RME). However, physiological parameters must be chosen appropriately. They should either be mean values (50th percentile values) or they should be 90th to 95th percentile values. However, they should not be mixed for a realistic and practical estimate of risk.

4.0 REFERENCES

U.S. Environmental Protection Agency, March 1990, "Exposure Factor Assessment, Part II," U.S. EPA, Washington, DC.

U.S. Environmental Protection Agency, January 1992, "Dermal Exposure Assessment: Principles and Applications", EPA/600/8-91/011B, Exposure Assessment Group, Office of Health and Environmental Assessment, U.S. EPA, Washington, DC.

7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

BERYLLIUM GUIDANCE

SUPPLEMENT NO. 94-013
REVISION NO. 1

AUGUST 29, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000097

Title: Beryllium Guidance	
SUPPLEMENT NO. 94-013 REVISION NO. 1	E-7312
Effective Date: August 29, 1994	Page 1 of 6

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
03/31/94	0	Provides the guidance for calculating PRGs for beryllium
08/19/94	1	Revised to provide PRGs and dermal risk assessment guidance for beryllium based on negotiations with the U.S. Environmental Protection Agency.

1.0 OBJECTIVE

Questions have been raised about beryllium and beryllium compounds with regard to risk assessments at the Fernald Environmental Management Project (FEMP). Of particular concern are values that were recommended by the U.S. Environmental Protection Agency's (EPA's) Environmental Criteria and Assessment Office (ECAO) for assessing beryllium exposure from dermal contact with soils. The objective of this Supplemental Guidance is to identify the beryllium issues at the FEMP, to discuss the resolution of these issues based on negotiations with EPA, and to provide guidance on procedures for calculating dermal risk of beryllium and beryllium compounds in future risk assessments.

2.0 SUPPLEMENTAL GUIDANCE

The oral dose-response factors derived for beryllium were based on drinking water (oral ingestion) studies. It was agreed upon by EPA and the U.S. Department of Energy (DOE) that since no adjustments were made on the dose-response calculated for oral ingestion of beryllium compounds during from these studies, it appears that these studies assume an absorbed dose. Therefore, no adjustments are necessary when converting the oral slope factor for use as a dermal slope factor.

This position is considered to be adequately protective for assessing risk from dermal contact with beryllium, given the information provided by the Agency for Toxic Substances and Disease Register (ATSDR 1991), the Integrated Risk Information System [IRIS (EPA 1994a)] and ECAO (EPA 1993; 1994b). This process will be followed during all future risk assessments involving beryllium and beryllium compounds in remedial investigations and feasibility studies at the FEMP.

3.0 SUPPORTING INFORMATION

DOE first requested dermal absorption factors from ECAO for COCs when preparing the Operable Unit 4 Remedial Investigation (EPA 1993b). A copy of a portion of this memorandum is provided as Attachment 1. Based on ECAO's review of data for beryllium, they recommended that risk assessments at the FEMP use a gastrointestinal absorption fraction of 0.01 (one percent) and a dermal absorption fraction of 0.01 (one percent). No opinion was given whether the oral dose-response for beryllium was based on an absorbed dose or an administered dose. DOE assumed that the beryllium dose-response was based on an administered dose and calculated dermal dose-response factors for beryllium using an adjustment on the oral dose-response to calculate absorbed dose-response factors according to RAGS guidance (EPA 1989). This procedure was used in the baseline risk assessments for Operable Units 1, 2, and 4. However, upon evaluation of the conclusions of these baseline risk assessments, it was determined that beryllium was contributing a significant proportion to the total risk for each operable unit. For example, in Operable Unit 2, beryllium accounted for approximately 65 percent or more of the total risk for some receptors. Dermal contact with soil accounted for 95 percent to 97 percent of risk attributed to beryllium. However, the levels detected in media responsible for the exposure were only elevated slightly above background. This finding significantly impacted the Operable Unit 2 Feasibility Study. A significant increase in soil volumes would be required to mitigate potential risk posed by beryllium via dermal contact. DOE reviewed the status of beryllium with regard to the FEMP and approached EPA Region V regarding the uncertainty inherent in this methodology.

Specific dose-response values are not available from the IRIS, Health Effects Assessment Summary Tables (HEAST), or ECAO for assessing dermal exposure to constituents. Therefore, the risk assessor conducts an independent search to evaluate the potential for exposure and risk from dermal contact (EPA 1992). This evaluation includes the search for relevant studies for developing dermal dose-response factors and dermal absorption factors. Information published by the ATSDR is given the highest priority. If information is unavailable or incomplete from ATSDR, the risk assessor must conduct an independent review of the toxicology, epidemiology, and pathology literature for information relevant to dermal exposure regarding the constituent of concern (COC). If inadequate data exists to calculate dose-response factors for the dermal pathway, then Risk Assessment Guidance for Superfund [RAGS (EPA 1989)] recommends calculating a dermal dose-response factor based on the established oral-dose response factor.

A series of dialogues were held between the EPA and DOE during the time period from April 12, 1994 to July 20, 1994. A summary of these dialogues follow:

- April 12, 1994 Meeting between EPA and DOE (Attachment 2)
  In this meeting, EPA was made aware of the issues with the dermal pathway. DOE presented a summary of the Supplemental Guidance for Assessing Dermal Risk to Beryllium. It was stressed to EPA that, although there is not a significant source of beryllium at the site, it is one of the primary risk drivers for Operable Unit 2 and the outlying areas of Operable Unit 5. Also, it was pointed out that the background sampling program may not be representative of the FEMP soils as indicated by higher frequency of detection for beryllium and higher concentrations in "cleaner" areas of the FEMP. As a result, it was indicated that beryllium has the potential to drive remedial activities for these operable units.

  It was pointed out that the dermal exposure pathway accounted for approximately 97 percent to 99 percent of the total dose from beryllium exposure. No data exists to quantify dose-response from beryllium; therefore, at this time, the dermal pathway is only considered in a qualitative manner for this compound. DOE stated that it cannot support such significant risk management decisions based on this "qualitative" exposure pathway. Therefore, DOE informed EPA that the current draft of the Operable Unit 2 Feasibility Study would be based on the proposed alternative method. The EPA Region V Senior Toxicologist stated that EPA would look into these issues based on a "California Study" on values for dermal contact and that EPA Region V would contact the ECAO for consultation on this matter.

- May 24, 1994 Memorandum from Joan Dollarhide ECAO (Attachment 3)
  ECAO reexamined the oral and dermal absorption factors for beryllium and the potential for carcinogenicity for beryllium from the dermal pathway. ECAO concluded that, although quantitative data is limited on this matter, existing data supports their original position on dermal and oral absorption factors.

- July 7, 1994 Meeting between EPA and DOE
  DOE presented an issue paper (Attachment 4) outlining issues pertaining to ECAO and beryllium impacts on the FEMP site. At the conclusion of the presentation, the EPA Region V Senior Toxicologist requested that DOE provide example calculations using 1 percent (ECAO proposed value) and 0.1 percent (default value for metals) for the dermal absorption rate. Concurrent with this analysis, EPA would research the relevant studies summarized by IRIS to review the basis for the current oral slope factor.

  DOE provided example calculations to EPA via a facsimile dated July 14, 1994 (Attachment 5).

- July 20, 1994 Conference Call between DOE and EPA
  A conference call was held between DOE and EPA to discuss the example calculations sent to EPA by DOE and to discuss the review of IRIS by the EPA Region V Senior Toxicologist. In this discussion, the EPA Region V Senior Toxicologist stated that the calculations presented by DOE appear correct. She concluded that the dermal exposure pathway appeared to pose a higher than expected risk from background concentrations of beryllium in soil. The EPA Region V Senior Toxicologist's review of studies presented in IRIS suggest that the oral dose-response factors were based on absorbed dose and not administered dose. Therefore, it was concluded that no adjustment was needed to use the oral dose response factor to calculate dermal dose response to beryllium.

- EPA instructed DOE to use this method (Attachment 6) in their approval letter for the Operable Unit 1 FS dated July 27, 1994.

4.0 REFERENCES

Agency for Toxic Substances and Disease Registry (ATSDR), 1991, "Toxicological Profile for Beryllium," ATSDR, U.S. Public Health Service, Atlanta, GA.

U.S. Environmental Protection Agency, 1989, "Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A: Interim Final" EPA/540/1-89/002, EPA, Washington, DC.

U.S. Environmental Protection Agency, 1992, "Dermal Exposure Assessment: Principles and Applications," EPA/600/8-91/011B, Exposure Assessment Group, Office of Health and Environmental Assessment, U.S. EPA, Washington, DC, p. 9-2.

U.S. Environmental Protection Agency, 1993a, "Health Effects Assessment Summary Tables, FY-1991," OERR 9200.6-303(91-1), EPA, Washington, DC.

U.S. Environmental Protection Agency, 1993b, Memorandum from Joan Dollarhide, ECAO, to Pat VanLeeuwan, Region V Toxicologist, "...Oral and Dermal Absorption Factors for Multiple Chemicals (FEMP O.U.#4/Fernald, Ohio)," EPA, Environmental Criteria and Assessment Office, Cincinnati, Ohio.

U.S. Environmental Protection Agency, 1994a, "Integrated Risk Information System (IRIS)", computer database, EPA, Washington, DC.

U.S. Environmental Protection Agency, 1994b, Memorandum from Joan Dollarhide, ECAO, to Pat VanLeeuwan, Region V Toxicologist, "Review of Oral and Dermal Absorption Factors and Assessment of Carcinogenicity by the Dermal Route for Beryllium, for the Feed Materials Production Center/Fernald, Ohio", EPA, Environmental Criteria and Assessment Office, Cincinnati, Ohio.

ATTACHMENT 1
ECAO BERYLLIUM RECCOMENDATIONS

7312

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
ENVIRONMENTAL CRITERIA AND ASSESSMENT OFFICE
CINCINNATI, OHIO 45268

MEMORANDUM:

DATE: July 21, 1993

SUBJECT: Chronic and Subchronic, Systemic and Carcinogenic, Oral and Inhalation Toxicity Information for 2-Hexanone (Methyl n-Butyl Ketone, CAS No. 591-78-6), Magnesium (CAS No. 7439-95-6), Tributyl Phosphate (CAS No. 126-73-8) and Mixed Xylenes (CAS No. 1330-20-7). Oral and Dermal Absorption Factors for Multiple Chemicals (FEMP O.U.#4/Fernald, OH)

FROM: Joan S. Dollarhide
Associate Director
Superfund Health Risk Technical Support Center
Chemical Mixtures Assessment Branch

TO: Pat VanLeeuwen
U.S. EPA
Region V

This memorandum is in response to your request for chronic and subchronic, systemic and carcinogenic, oral and inhalation toxicity values for contaminants found at the FEMP O.U. #4 in Fernald, Ohio.

We are currently preparing a provisional RfC for 2-hexanone; however, we were not able to complete this work within the short time frame for this request. If you are interested in seeing this information when it is complete, please let me know.

Attached please find the following information:

Attachment 1: Risk Assessment Issue Paper for: Derivation of a Provisional RfD for 2-Hexanone (Methyl n-Butyl Ketone, CAS No. 591-78-6)

Attachment 2a: Risk Assessment Issue Paper for: Systemic Toxicity Information for Magnesium (CAS No. 7439-95-4)

Attachment 2b: Risk Assessment Issue Paper for: Evaluation of Carcinogenicity of Magnesium (CAS No. 7439-95-4)

Attachment 3: Provisional Chronic RfD and Oral Slope Factor for Tributyl Phosphate (CAS No. 126-73-8)

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Sufficient evidence for the carcinogenicity of benzo[b]fluoranthene is available from animal testing. Increased tumor incidences at the injection site and at distant sites have been observed in mice following intraperitoneal injections of benzo[b]fluoranthene. Increased incidences of lung tumors occurred in rats given lung implants containing benzo[b]fluoranthene. Benzo[b]fluoranthene produced skin tumors when applied dermally to mice.

Benzo[b]fluoranthene is a Group B2 carcinogen - Probable Human Carcinogen based on inadequate evidence in humans and sufficient evidence for carcinogenicity in animal assays (U.S. EPA, 1993).

Oral-to-dermal extrapolation is not appropriate for benzo[b]fluoranthene because of the evidence that dermal exposure to benzo[b]fluoranthene causes skin cancer and the uncertainty that the oral slope factor will protect against the local carcinogenic effect of dermally applied benzo[b]fluoranthene.

REFERENCES FOR BENZO[b]FLUORANTHENE:

U.S. EPA. 1990. Drinking Water Criteria Document for Polycyclic Aromatic Hydrocarbons (PAHs). Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Drinking Water, Washington, DC. Final Draft.

U.S. EPA. 1993. Integrated Risk Information System. Online. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH.

ATSDR (Agency for Toxic Substances and Disease Registry). 1990. Toxicological Profile for Polycyclic Aromatic Hydrocarbons. U.S. Public Health Service. Atlanta, GA.

(10/09/92)

Beryllium

Data regarding dermal absorption of beryllium were reviewed by U.S. EPA (1987b), ATSDR (1988) and ATSDR (1991). According to ATSDR (1991), skin ulceration in workers exposed to beryllium occured only after the skin was abraded (Williams, et. al.,1987) It is unlikely that beryllium is absorbed through intact skin. An experiment in rats showed that small amounts of beryllium can be absorbed through the tail, but did not determine an absorption factor. Because of the chemical properties of beryllium, it is unlikely that significant amounts could be absorbed through the

skin. Dermal absorption values for other metallic salts ($CrCl_3$, Na_2CrO_4, $CoCl_2$, $ZnCl_2$, $CdCl_2$, $HgCl_2$) in guinea pigs were all less than 2% (Shah and Guthrie, 1986). These values would be expected to be even lower following exposure to the compound in soil due to adsorption of the cations to soil particles. Therefore, the "proposed" dermal absorption factor of 1% appears to be reasonable for beryllium.

U.S. EPA (1980, 1987a, 1987b) and ATSDR (1988) reviewed the available data regarding absorption of beryllium from the gastrointestinal tract. No data were available for humans. However, based on studies in animals, oral absorption of beryllium in humans is expected to be very limited. Experiments in animals suggest that <1% of ingested beryllium is absorbed through the gut, with the more soluble salts, such as beryllium sulfate, being absorbed better than insoluble salts, such as beryllium oxide. In one study, low absorption of beryllium sulfate was attributed to formation of phosphate precipitate in the intestine. The authors of this study surmised that absorption of beryllium occurred predominantly in the stomach. Because absorption from the stomach would be expected to depend on gastric emptying time, which can vary widely, this finding suggests that beryllium absorption might be subject to large variations. However, such variations are not seen in the existing data. The "proposed" oral absorption factor of 1% appears to be reasonable, given the existing data.

REFERENCES FOR BERYLLIUM

ATSDR (Agency for Toxic Substances and Disease Registry). 1988. Toxicological Profile for Beryllium. ATSDR, U.S. Public Health Service, Atlanta, GA.

ATSDR (Agency for Toxic Substances and Disease Registry). 1991 Toxicological Profile for Beryllium. Public Comment Draft. ATSDR, U.S. Public Health Service, Atlanta, GA.

Shah, P.V. and F.E. Guthrie. 1986. Dermal and gastrointestinal absorption of environmental contaminants. In: Reviews in Environmental Toxicology 2. E. Hodgson, Ed. Elsevier, N.Y.

U.S. EPA. 1980. Ambient Water Quality Criteria Document for Beryllium. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH. EPA 440/5-80/024. PB81-117350.

U.S. EPA. 1987a. Health Effects Assessment for Beryllium and Compounds. Prepared by the Office of Health and Environmental

ATTACHMENT 2
MEETING NOTES FROM APRIL 12, 1994
MEETING BETWEEN EPA AND DOE

U. S. DEPARTMENT OF ENERGY
FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

FERMCO CONTRACT
DE-AC05-92OR21972

MEETING NOTES

SUBJECT: RISK ASSESSMENT ISSUES

MEETING DATE: April 12, 1994

LOCATION: FERMCO Fernald Office

ISSUE DATE: April 18, 1994 File Record Storage Copy 104.5

DISTRIBUTION: + Attendees ++ Part-time * Author of Notes

+ Ken Alkema	+ Rob Janke, DOE-FN	Joe Prince
* Kirk Gribben	Elaine Merrill	+ Jim Saric, EPA
Matthew Hnatov	Keith Nelson	+ Pat Van Leeuwan, EPA
+ Randy Janke, DOE-FN	Marc Nelson	Steve Weldert

The following is a summary of the risk assessment meeting with DOE and EPA.

Supplemental Guidance on PRG/PRL Development

Randy Janke, DOE-FN, presented a brief overview of the Supplemental Guidance on Preliminary Remediation Goals/Proposed Remediation Levels Development. After a brief introduction regarding the purpose of the policy, Figure 1, which outlines the process, was discussed.

Jim Saric, EPA, stated that Supplemental Guidance to the Risk Assessment Work Plan Addendum provided by the Fernald Environmental Management Project (FEMP) would not be officially approved by EPA but would be used as a tool by EPA to review procedures used in FEMP Remedial Investigation (RI)/Feasibility Study (FS) reports. It was pointed out by EPA that the Supplemental Guidance would be an asset to the overall project.

Pat Van Leeuwan, EPA, stated that she did not have the time to review the Supplemental Guidance on PRG/PRL Development but provided some observations. First, the risk-based/Applicable or Relevant and Appropriate Requirement (ARAR)-based PRG identified in the figure is really a site-specific PRG, which usually is the second step. Step 1 is typically considered an EPA Part B-based PRG. Therefore, she recommends we identify the first step as a site-specific risk-based PRG. She also commented on the use of "modified PRG". She indicates that a PRG with modifiers and background should be considered a PRL. However, we all agreed that the procedure rather than the terminology was the issue. Overall, she agreed with the procedure.

Paper on Recreational Use Scenarios for Operable Unit 5 Feasibility Study

Kirk Gribben presented a summary/overview of the paper discussing potential recreational scenarios for the FEMP. EPA had indicated they reviewed this paper prior to the meeting. EPA suggested they liked the paper and thought the scenarios were reasonably conservative. They made recommendations for referencing text/tables/figures if the paper were released for public review.

MEETING NOTES - Continued

Item/Description

However, FERMCO stressed that this paper outlined the objectives agreed upon in the February 24, 1994 meeting and that it was prepared primarily for technical review between EPA/DOE/FERMCO. FERMCO told EPA that the details provided in this paper would not be presented in the Operable Unit 5 FS but would be used in the FS for evaluating residual risk. EPA agreed to further review the paper and submit comments in a timely manner on the exposure assumptions.

Supplemental Guidance on Assessing Risk from Dermal Contact to Beryllium
Kirk Gribben presented a summary of the Supplemental Guidance for Assessing Dermal Risk to Beryllium. It was stressed to EPA that, although there is not a significant source of beryllium at the site, it is one of the primary risk drivers for Operable Unit 2 and the outlying areas of Operable Unit 5. Also, it was pointed out that the background sampling program may not be representative of the FEMP soils as indicated by higher frequency of detection for beryllium and higher concentrations in "cleaner" areas of the FEMP. As a result, it was indicated that beryllium has the potential to drive remedial activities for these operable units.

It was pointed out the dermal exposure pathway was accounting for approximately 97 percent to 99 percent of the total dose. No data exists to quantify dose-response from beryllium; therefore, at this time, the dermal pathway is considered qualitative for beryllium. FERMCO stated that it cannot support such significant risk management decisions based on this "qualitative" exposure pathway. Therefore, FERMCO informed EPA that the Operable Unit 2 FS would be based on the proposed alternative method. EPA was made aware of the issues with the dermal pathway; Pat Van Leeuwan stated that she would look into these issues based on a "California Study" on values for dermal contact and that she will also contact Environmental Criteria and Assessment Office (ECAO).

Operable Unit 3 Baseline Risk Assessment
Rob Janke, DOE-FN, discussed the need for a baseline risk assessment for Operable Unit 3 with EPA. He stated that since an interim removal action has been decided upon for the buildings, DOE sees no need for a baseline risk assessment. DOE also offered to move the schedule forward. EPA agreed, but final details will be worked out with further meetings between DOE and EPA.

Other
EPA is still looking into the use of the proper value for total body surface area. Final resolution may not be made prior to the Operable Unit 5 RI or FS.

ATTACHMENT 3
MAY 24, 1994 MEMORANDUM FROM JOAN DOLLARHIDE, ECAO

7312

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
ENVIRONMENTAL CRITERIA AND ASSESSMENT OFFICE
CINCINNATI, OHIO 45268

MEMORANDUM

DATE: May 24, 1994

SUBJECT: Review of Oral and Dermal Absorption Factors and Assessment of Carcinogenicity by the Dermal Route for Beryllium, for the Feed Materials Production Center/Fernald, OH

FROM: Joan S. Dollarhide
Director
Superfund Health Risk Technical Support Center
Chemical Mixtures Assessment Branch

TO: Pat Van Leeuwen
U.S. EPA
Region V

This memorandum responds to your request for the Superfund Health Risk Technical Support Center to reexamine the oral and dermal absorption factors for beryllium. In addition, we have assessed the liklihood of beryllium inducing cancer by the dermal route.

Please find attached the following Risk Assessment Issue Paper:

Attachment **Risk Assessment Issue Paper for: Review of Oral and Dermal Absorption Factors and Assesment of Carcinogenicity by the Dermal Route for Beryllium (CASRN 7440-41-7)**

Please contact the Superfund Health Risk Technical Support Center at (513) 569-7300 with any additional questions.

cc: J. Konz (5204G)

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Attachment

DRAFT #2 (94-029/05-12-94)

Risk Assessment Issue Paper for: Review of Oral and Dermal Absorption Factors and Assesment of Carcinogenicity by the Dermal Route for Beryllium (CASRN 7440-41-7)

BERYLLIUM ABSORPTION AND CARCINOGENICITY BY THE DERMAL ROUTE

Information from the recent Drinking Water Criteria Document (U.S. EPA, 1991) and the Toxicological Profile for Beryllium (ATSDR, 1993) were consulted. SRC performed and screened updated literature searches on the following databases: TOXLINE and Cancerline, 1991-present (cancer strategy with dermal keywords) and MEDLINE, 1991-present (cancer strategy). No cancer studies of beryllium exposure by the dermal route were identified. Additional searches were conducted for recent information on oral and dermal absorption of beryllium on the following databases: MEDLINE and TOXLINE, 1965-present. No new studies on the oral or dermal absorption of beryllium were identified.

ORAL AND DERMAL ABSORPTION

Although it is generally accepted that little beryllium is absorbed when exposure occurs orally or dermally (Reeves, 1989; U.S. EPA, 1991; ATSDR, 1993), there are few studies designed specifically to examine beryllium absorption. These studies are limited by the use of small groups of animals, low recovery of beryllium, and single dose or short-term duration. In addition, there is considerable uncertainty because absorption of beryllium may be dose-dependent, may vary with age, nutritional status and exposure to other metals, and will likely vary depending on gastrointestinal contents (e.g., empty or with food).

Oral Absorption

Reeves (1965) administered male Sprague-Dawley rats (4/group) 0, 3.3 or 33 ppm beryllium sulfate in drinking (tap) water for up to 24 weeks. Average daily intake as determined by the authors was 0, 6.6 and 66.6 μg beryllium. One rat/group was sacrificed at 6, 12, 18 and 24 weeks of exposure and the heart, lungs, kidneys, spleen, gastrointestinal tract, one femur, blood and part of the liver analyzed for beryllium. Urine and feces were collected daily, but excretion data are reported in detail only for the sacrifice intervals above. Recovery of beryllium (total output as measured in organs, urine and feces/total intake) at 6-24 weeks was 76-87% in the low dose group and 60-91% in the high dose group. No explanation was given by the author for the low recovery, although adherence of beryllium to

the drinking water vessel or the methods used to quantitate beryllium in tissues and excreta (spectrographic) might account for some of the losses. Feces contained 96-99% of the recovered beryllium, suggesting that most of the beryllium passed through the gut unabsorbed. Other explanations for the high fecal beryllium content (e.g., excretion of absorbed beryllium) were not examined. Oral absorption, estimated as the beryllium measured in organs plus urine/recovered beryllium, was 0.9-3.6% in the low dose group and 0.3-0.6% in the high dose group. The author postulated that ingested beryllium is mostly likely absorbed in the acidic environment of the stomach, where it is in the ionized form, and passes through the intestines as the precipitated phosphate because of the neutral pH. However, there are no data that localize beryllium absorption to a specific area of the GI tract.

Furchner et al. (1973) intubated male Sprague-Dawley rats (6/group) and RF mice female (12/group), and fed male beagles (4/group) a gelatin capsule, and male *Macaca speciosa* monkeys (3/group) a sugar cube, with a single dose of radioactive beryllium chloride. Retention of radioactive beryllium was measured in excreta, whole body and tissue for up to 3 days following oral administration. Groups of rats (6/group), mice (12/group) and dogs (4/group) of the same sex and female monkeys (3/group) of the same species were given a single intravenous dose of radioactive beryllium. In addition, groups of rats and mice were given single intraperitoneal doses of radioactive beryllium. Retention of radioactive beryllium was measured for 239-273 days or 364-380 days in those animals injected intravenously or intraperitoneally, respectively. Beryllium was more rapidly lost (shorter half-life) in all species when beryllium was administered orally than when administered parenterally. Two-day cumulative excretion in rats receiving the single intragastric dose was 0.11% and 104.7% in the urine and feces, respectively. Urinary output was 0.24, 0.38 and 3.71%, and fecal output was 98.42, 108.83 and 102.41% in mice, dogs and monkeys, respectively, 1-2 days following oral administration. The author estimated gut absorption from the short-term urinary data to be 0.6%. (The value of 0.6% was used by U.S. EPA (1991) to determine an oral quantitative risk estimate by a route-to-route extrapolation from the inhalation route in support of the estimate determined using data from Schroeder and Mitchener [1975]). Cumulative urinary and fecal excretion at 6-7 days in animals dosed parenterally indicate that fecal excretion of beryllium occurs, although to a lesser extent (1/10 to 1/3 depending on the species) than urinary excretion. Comparison of excretion amongst the exposure routes suggests that if beryllium were absorbed when ingested, a small fraction might be excreted through the feces. This implies that some approaches taken to estimate oral absorption using only urinary measures or assuming all gut beryllium was unabsorbed may underestimate absorption.

Furchner et al. (1973) also quantitated the distribution of radioactive beryllium in bone (femur), viscera, pelt and muscle at 2, 4, 6 and 8 weeks of exposure in 16 male Sprague-Dawley rats after daily oral ingestion of a radioactive beryllium saccharin-glucose solution. At all time points, the bone retained more than 40% of the body burden. The author estimated gut absorption in rats from this study to be approximately 0.4%, based on

the ratio of urinary to fecal excretion assuming no excretion of absorbed beryllium into the feces.

In a study designed to compare the distribution of radioactive beryllium when adhered to carbon particles and when in a beryllium chloride solution (dissolved in Tween 80), LeFevre and Joel (1986) separately administered both forms by single dose gavage (dose not specified, 0.25 ml volume) to weanling and aged female Swiss albino mice. Distribution of radioactivity was measured in whole gut with contents, liver, lungs, kidneys, mesentery with lymph nodes, blood, carcass, feces and urine at 4 hours, 1, 2, 5 and 14 days (8 mice/age group at each time point) following administration. Radioactivity was highest in the whole gut in both age groups at all time points with both forms of beryllium, suggesting to the authors that there was rapid passage of unabsorbed beryllium. In nonintestinal tissues (liver, lungs, kidneys, mesentery, blood and eviscerated carcass), $\leq$0.3% and $\leq$0.01% of the administered radioactivity was reported in mice receiving beryllium chloride and beryllium-carbon particles, respectively. These data indicate that uptake of beryllium following intragastric administration is small.

Information from toxicokinetic and animal toxicity studies suggest beryllium is absorbed when ingested. The lesser acute toxicity of beryllium by the oral route than when administered by other routes has been attributed to its low intestinal absorption (U.S. EPA, 1991). Subchronic and chronic animal studies have shown reduced body weights following oral administration of beryllium (U.S. EPA, 1991). Effects of beryllium on the bone include rickets (Branion et al., 1931; Guyatt et al., 1933; Kay and Skill, 1934; Businco, 1940), although this has been postulated to be the result of an indirect effect of the interaction of beryllium with phosphate (U.S. EPA, 1987) and/or with alkaline phosphatase (U.S. EPA, 1991). Animal studies using oral administration have shown that ingested beryllium is widely distributed, primarily to the bone, lung, liver and kidney (reviewed in U.S. EPA, 1991; ATSDR, 1993), and accumulates mainly in the skeleton (Reeves, 1965; Furchner et al., 1973). Concentrations were highest in bone, liver and kidney in people occupationally exposed to beryllium (Tepper et al., 1961). The physicochemical state of beryllium determines the main site of deposition when administered to animals by injection (U.S. EPA. 1987; U.S. EPA, 1991); soluble beryllium distributes to the skeleton (Klemperer et al., 1952). Beryllium is distributed to the bone following intravenous, intramuscular or intraperitoneal injection into rats (Crowley et al., 1949; Klemperer et al., 1952; Furchner et al., 1973) and intratracheal administration in rats (Spencer et al. 1972). Beryllium sulfate administered to rats in the drinking water (Reeves, 1965) or as an aerosol to rats and guinea pigs (Zorn et al., 1977) showed skeletal uptake of beryllium. When administered orally or by inhalation to rats, beryllium appears to be excreted primarily in the feces (U.S. EPA, 1991). These studies support the hypothesis that beryllium can be absorbed following oral exposure, albeit to a small degree, and can distribute throughout the body to produce an adverse health effect.

Given the constraints of the database, and relying on the data of Reeves (1965) and Furchner et al. (1973), it appears that an estimate of 1% for the oral absorption of beryllium is reasonable.

Dermal Absorption

It is generally accepted that beryllium absorption through unbroken skin, even following prolonged or repeated contact, adds insignificant amounts of beryllium to the body (U.S. EPA, 1991; ATDSR, 1993). There are no definitive studies to refute this contention. It has been suggested, however, that beryllium absorption through open wounds can be substantial (i.e., 12-27% in 24 hours) (Ivannikov et al., 1982).

Contact dermatitis from occupational dermal exposure in humans is well-known (U.S. EPA, 1991; ATSDR, 1993). Delayed hypersensitivity reactions have also been shown in guinea pigs following dermal or intradermal sensitization (U.S. EPA, 1991; ATSDR, 1993). In a study designed to examine the delayed allergic reaction of beryllium, Belman (1969) reported that beryllium binds to tissue protein, nucleic acids and alkaline phosphatase in guinea pig epidermis *in vitro*. Further investigation is needed to associate these findings with local or systemic toxic effects.

Petzow and Zorn (1974) measured the absorption of aqueous beryllium chloride and radioactive beryllium chloride solutions through the tail skin of rats (other details not provided), distribution to organs (muscle, kidney, liver, lung, spleen, blood, heart, stomach, intestine), and excretion in urine. Beryllium was detected in all organs examined, indicating it was absorbed through the skin and eliminated in the urine and feces.

Studies in animals wherein beryllium was injected intradermally or subcutaneously suggest that beryllium, if it can penetrate the epidermis, could be distributed to sites distant from the skin. The following studies demonstrate the effects associated with subcutaneous injection:

Marx and Burnell (1973) intradermally injected guinea pigs (sex not specified) biweekly for 12 weeks with aqueous solutions of beryllium sulfate. Following sensitization, animals were sacrificed (number not specified). Histological lesions in the lung and hemosiderin and focal hyperplasia in the spleen were noted.

Moritz et al. (1982) injected guinea pigs intradermally with 10 μg/injection of beryllium fluoride twice per week for 6 weeks. Beryllium was found in mononuclear cells of the lung but not in that cell type in the spleen or blood.

Sakaguchi et al. (1993) subcutaneously injected male JCL:ICR mice with radioactive beryllium chloride (0.5 μg/mouse). Excretion in urine and feces and distribution in liver, kidneys, spleen and femurs of radioactive beryllium were measured at days 1 (9/group) and 7 (4/group) following injection. Recovery of beryllium was 88%. At day 1, 1.5% and 24% of the recovered beryllium was detected in the feces and urine, respectively. At day 7, 2.8% and 37% of the recovered beryllium in feces and urine was detected. The authors suggested that the beryllium measured in the feces could be due to contamination of the feces with

urine due to their collection method. The highest concentration of beryllium was detected in the femur with lesser concentrations in the liver, kidneys and spleen at both time points.

With essentially no data available, a dermal absorption value for beryllium cannot be determined. The sparse data for other metals suggests that 1% dermal absorption for beryllium is likely to be appropriate. Hammerstrom (1993) concludes that default values of 1% for dermal absorption of inorganics seems reasonable.

BERYLLIUM CARCINOGENICITY

The U.S. EPA carcinogenicity assessment for beryllium is on IRIS (U.S. EPA, 1994). Information on IRIS is extensively peer-reviewed and represents an Agency consensus. As delineated in Chapter 7 of U.S. EPA (1989), information on IRIS supersedes all other sources and precludes the need to consult other sources for toxicity information, such as those discussed in the *Supplemental Guidance to the Risk Assessment Work Plan Addendum, Beryllium Guidance, June 1992* (FEMP, 1994).

Beryllium is classified as a B2, probable human carcinogen, based on inadequate evidence in humans but sufficient evidence in animals. The human studies on beryllium-exposed workers, all based on the same basic cohort, are considered inadequate because of deficiencies, such as the lack of adjustment for smoking, that limit any definitive conclusion as to an association between beryllium exposure and lung cancer.

Sufficient evidence of carcinogenicity in animals is based on the induction of lung cancer via inhalation in rats and monkeys, and of osteosarcomas in rabbits reported in numerous studies via intravenous or intramedullary injection. Additionally, an increase in grossly observable tumors in rats and an increase in leukemias/lymphomas in mice receiving beryllium in drinking water (although not statistically significantly elevated), and an increase in reticulum cell sarcomas in rats fed beryllium in the diet, have been reported. While each of the animal studies has limitations, taken as a whole, the findings of lung cancer and osteosarcoma in several species, exposed by several routes, in numerous studies, and the findings of tumors at distant sites following oral ingestion, provide sufficient evidence that beryllium is carcinogenic in animals.

In genotoxicity tests, beryllium has produced both positive and negative findings depending on the solubility of the compound and the test system (U.S. EPA, 1991; ATSDR, 1993; U.S. EPA, 1994). While beryllium does not induce mutations in bacteria and yeast, it has been shown to cause gene mutations, chromosomal aberrations and sister chromatid exchange in mammalian somatic cells (U.S. EPA, 1991).

Quantitative risk estimates for beryllium by both the inhalation and oral routes are available on IRIS. The oral quantitative estimate is derived from a chronic drinking water study in male rats wherein an increase, although not statistically significant, in gross tumors

of all sites combined was found. EPA acknowledges limitations in this estimate in the Discussion of Confidence for the oral quantitative estimate on IRIS. The Drinking Water Criteria Document for Beryllium (U.S. EPA, 1991), the supporting document for the IRIS summary, states that "...no definitive evidence exists that correlated the ingestion of beryllium with tumor appearance since it has not been tested orally at the MTD." U.S. EPA (1991) cautions in the use of the quantitative estimate due to the severe limitation in the derivation.

Thus, while the evidence supports the probability that beryllium by the oral route is carcinogenic in humans, the quantitative estimate of risk for oral exposure is highly uncertain and likely conservative.

DERMAL CARCINOGENICITY

The weight-of-evidence for the B2 classification, probable human carcinogen, for beryllium has been considered and verified by the EPA's CRAVE Work Group and is on IRIS (U.S. EPA, 1994). Similarly, IARC (1987) has classified beryllium in Group 2A (human data limited, animal data sufficient), and the U.S. DHHS (1991) lists beryllium and certain beryllium compounds as having sufficient evidence of carcinogenicity in experimental animals.

In the weight-of-evidence classification of carcinogens by EPA, provisions are not made for separate categorization by route of exposure. Unless a substance has been demonstrated not to be a carcinogen by a particular route, in order to be protective of human health, it is assumed that if a chemical has carcinogenic potential by one exposure route, it also has carcinogenic potential by other routes.

Beryllium compounds can produce lesions on the skin at the point of contact. Whether these lesions can progress to tumors has not been directly investigated. When administered subcutaneously or intradermally in animals, beryllium is distributed throughout the body. While little beryllium may be absorbed dermally, based on the nonthreshold assumption, any amount absorbed may pose a potential risk. Given that animal studies by various routes of exposure provide evidence of tumor production at a site distant from the portal of entry, it is not unreasonable to speculate that dermal exposure to beryllium could also produce distant site tumors. Since no threshold dose has been demonstrated for beryllium, any exposure to beryllium theoretically would represent some finite risk.

REFERENCES

ATSDR (Agency for Toxic Substances and Disease Registry). 1993. Update Toxicological Profile for Beryllium. U.S. Public Health Service. Atlanta, GA. T-92/04.

Belman, S. 1969. Beryllium binding of epidermal constituents. J. Occup. Med. 11: 175-183.

Branion, H.D., B.L. Guyatt and H.D. Kay. 1931. Beryllium rickets. J. Biol. Chem. 92: 11. (cited in U.S. EPA, 1991)

Businco, L. 1940. The rickets-producing effect of beryllium carbonate. Rass. Med. Ind. 11: 417-442. (cited in U.S. EPA, 1991)

Crowley, J.F., J.G. Hamilton and K.J. Scott. 1949. The metabolism of carrier-free radioberyllium in the rat. J. Biol. Chem. 177: 975-984. (cited in U.S. EPA, 1991)

Fernald Environmental Management Project. 1994. Supplemental Guidance to the Risk Assessment Work Plan Addendum, June 1992. Beryllium Guidance. U.S. Department of Energy, Fernald Field Office.

Furchner, J.E., C.R. Richmond and J.E. London. 1973. Comparative metabolism of radionuclides in mammals. VIII. Retention of beryllium in the mouse, rat, monkey and dog. Health Physics. 24: 293-300.

Guyatt, B.L., H.D. Kay and H.D. Branion. 1933. Beryllium rickets. J. Nutr. 6: 313-324. (cited in U.S. EPA, 1991)

Hammerstrom, K.A. 1993. Memorandum to J.S. Dollarhide from K.A. Hammerstrom dated March 18, 1993. Review of Position Paper on Proposed Modifications to Soil Clean-Up Levels, American Chemical Services Site, Griffith, Indiana.

IARC. 1987. International Agency for Research on Cancer. IARC monographs on the evaluation of carcinogenic risk of chemicals to humans. Supplement 7: Beryllium and beryllium compounds. Lyon, France: World Health Organization. pp. 127-128.

Ivannikov, A.T., B.A. Popov and I.M. Parfenova. 1982. [Resorption of soluble beryllium compounds through the injured skin]. Gig. Tr. Prof. Zabol. 9: 50-52. (cited in Reeves, 1989)

LeFevre, M.E. and D.D. Joel. 1986. Distribution of Label after Intragastric Administration of ^{7}Be-labeled carbon to weanling and aged mice. Proc. Soc. Exp. Biol. Med. 182: 112-119.

Kay, H.D. and D.I. Skill. 1934. Beryllium rickets (11). The prevention and cure of beryllium rickets. Biochem. J. 28: 1222-1229. (cited in U.S. EPA, 1991)

Klemperer, F.W., A.P. Martin and R.W. Liddy. 1952. The fate of beryllium compounds in the rat. Arch. Biochem. Biophys. 41: 148-152. (cited in U.S. EPA, 1991)

Marx, J.J. and R. Burrell. 1973. Delayed hypersensitivity to beryllium compounds. J. Immunol. 111: 590-598.

Moritz, E.D., D. Pompliano, D. Harrison and W.W. Crystal. 1982. Selective lung accumulation of beryllium following exposure through a noninhaled route. Am. Rev. Respir. Dis. 125 (4:2): 149. (cited in U.S. EPA, 1991)

Petzow, G. and H. Zorn. 1974. [Toxicology of beryllium-containing substances]. Chem. Ztg. 98: 236-241. (German translation)

Reeves, A.L. 1965. The absorption of beryllium from the gastrointestinal tract. Arch. Environ. Health. 11: 209-214.

Reeves, A.L. 1989. Beryllium: Toxicological research of the last decade. J. Am. Coll. Toxicol. 8(7): 1307-1313.

Sakaguchi, T., S. Sakaguchi, I. Nakamura and Y. Kudo. 1993. Distribution of radioisotopic beryllium in ice after administration by various routes of injection. J. Toxicol. Environ. Health. 39: 517-526.

Schroeder, H.A. and M. Mitchener. 1975. Life-term studies in rats: Effects of aluminum, barium, beryllium and tungsten. J. Nutr. 105: 421-427.

Spencer, H.C., S.B. McCollister, R.J. Kociba, C.G. Humiston and G.L. Sparschu. 1972. Toxicological evaluation of beryllium motor exhaust products. AMRL-TR-72-118. Aeromedical Res. Lab., Wright-Patterson AFB, Dayton, OH. 94 p. (cited in U.S. EPA, 1991)

Tepper, L.B., H.L. Hardy and R.I. Chamberlin. 1961. Toxicity of Beryllium Compounds. Elsevier Publishing Co., New York. (cited in U.S. EPA, 1991)

U.S. Department of Health and Human Services (DHHS). 1991. Sixth Annual Report on Carcinogens. Summary 1991. Prepared for National Institute of Environmental Health Sciences. Research Triangle Park, NC.

U.S. EPA. 1987. Health Assessment Document for Beryllium. Office of Health and Environmental Assessment, Environmental Health and Assessment Office. Research Triangle Park, NC. EPA 600/8-84/026F. NTIS PB88-179205.

U.S. EPA. 1989. Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A). Office of Emergency and Remedial Response. Washington, D.C. EPA/540/1-89/002.

U.S. EPA. 1991. Drinking Water Criteria Document for Beryllium. Office of Health and Environmental Assessment, Environmental Health and Assessment Office. Cincinnati, OH. Final. ECAO-CIN-D003.

U.S. EPA. 1994. Integrated Risk Information System (IRIS). Online. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office. Cincinnati, OH.

Zorn, H., Th. Stiefel and H. Diem. 1977. [The significance of beryllium and its compounds for occupational medicine professionals]. Zentralbl. Arbeitsmed. Arbeitsschutz Prophyl. 27: 83-88. (cited in ATSDR, 1993)

ATTACHEMENT 4
JULY 7, 1994 ISSUE PAPER PRESENTED AT EPA AND DOE MEETING

ASSESSMENT OF RISK FROM DERMAL EXPOSURE TO BERYLLIUM

Issues:

- Beryllium was not an important constituent in the source materials nor was it an important process constituent used onsite. The maximum concentration detected of beryllium in residues (OU4 - Silo 3) was 39.9 mg/Kg, waste pit contents (OU1 - Pit 4) was 50.6 mg/Kg, inactive flyash pile (OU2) was 8.7 mg/Kg, and in surface soils (OU5 - Production Area) was 5.7 mg/Kg.

- However, exposure to beryllium in soil accounts for between 25% to over 65% percent of the total risk in OU2. Beryllium is also one the principle constituents contributing to risk from exposure to soils outside of the production and waste storage areas in OU5. The pathway contributing the majority to overall risk is dermal contact.

- Background risk to beryllium, using EPA Part A (Appendix A) and ECAO default values (1% GI absorption and 1% dermal absorption) and a representative background concentration of 0.6 mg/Kg, yields a risk of 2.2×10^{-4}, for the on-property farmer. Thus, beryllium poses the highest risk from background for inorganic chemicals, and compared to background risk to radionuclides, beryllium is only exceeded by radium-226.

- The risk-based PRG for beryllium in soil is 0.0028 mg/Kg for the on-property farmer and 0.025 mg/Kg for the expanded trespasser. PRLs are indistinguishable from background.

- A review of methods from EPA Part A and using ECAO proposed values suggest that the intake from dermal exposure to beryllium accounts for over 95% of the total risk for the RME on-property farmer, and over 99% for the expanded trespasser. These observations, however, appear to conflict with existing data on dermal absorption of beryllium. A literature review suggests that absorption of beryllium through the skin is insignificant and this pathway is not expected to be important considering the physical properties of beryllium.

ATTACHMENT 5
EXAMPLE CALCULATIONS FOR BERYLLIUM

EXAMPLE CALCULATIONS FOR BERYLLIUM

1.0 EXAMPLE CALCULATIONS FOR DERMAL CONTACT AND INCIDENTAL INGESTION OF SOIL BASED ON DEFAULT PARAMETER VALUES

This section presents example calculations for calculating the incremental lifetime cancer risk from exposure to beryllium in soils. This example uses default exposure parameter values used for the FEMP for both the OU4 and OU1 RI/FSs.

1.1 Dermal Contact with Beryllium in Soil

An incremental lifetime cancer risk from dermal contact with beryllium in soil is calculated by first calculating a dermally applied dose with the equation:

$$DAD_{Be} = \frac{(Cs_{Be})\ (SA)\ (AF)\ (ABS)\ (EF)\ (ED)\ (CF)}{(BW)\ (AT)} \quad (1)$$

where:
- DAD_{Be} = Dermally absorbed dose for beryllium from contact with soil (mg/Kg/day);
- Cs_{Be} = Concentration of beryllium in soil (mg/Kg);
- SA = Surface area for dermal contact (cm^2/event);
- AF = Soil-adherence factor to skin (mg/cm^2);
- ABS_{Be} = Soil dermal absorption factor (unitless);
- EF = Exposure frequency (events/yr);
- ED = Exposure duration (years);
- CF = Unit conversion factor (10^{-6} Kg/mg);
- BW = Body weight (Kg); and
- AT = Averaging time (days).

Default values for these parameters are as follows. For illustration purposes, the background concentration for beryllium in surface soils will be used for this example.

- DAD_{Be} = [calculated below] (mg/Kg/day);
- Cs_{Be} = 0.6 mg/Kg [representative background concentration for beryllium in surface soils];
- SA = 5,750 cm^2/event [25% of 95th percentile value for body surface area of 23,000 cm^2 from Dermal Assessment Guidance, (EPA 1992)];
- AF = 1 mg/cm^2 [maximum of range from 0.2 to 1 from Dermal Assessment Guidance, (EPA 1992)];
- ABS_{Be} = 0.01 (unitless) [value for beryllium from ECAO, memo from Joan Dollarhide to Pat VanLeeuwen, July 21, 1993];
- EF = 350 events/yr [from Risk Assessment Work Plan Addendum (DOE, 1992)];
- ED = 70 years [from Risk Assessment Work Plan Addendum (DOE, 1992)];
- CF = 10^{-6} Kg/mg;
- BW = 70 Kg; [default value for adult from Superfund Risk Assessment Guidance (EPA

1989)] and

AT = 25,550 days [default value for assessing incremental lifetime cancer risk from exposure carcinogenic compounds assuming 70 year lifetime from Superfund Risk Assessment Guidance (EPA 1989)].

Substitution of these default parameters into Equation 1 gives a DAD_{Be} as follows:

$$DAD_{Be} = \frac{(0.6\ mg/Kg)\ (5{,}750\ cm^2)\ (1\ mg/cm^2)\ (0.01)\ (350\ d/yr)\ (70\ yrs)\ (10^{-6})}{(70\ Kg)\ (25{,}550\ d)} \quad (2)$$

or:

$$DAD_{Be} = 4.73x10^{-7} \quad (3)$$

The incremental lifetime cancer risk (ILCR) from exposure to beryllium via dermal contact is calculated with the equation:

$$ILCR_{der_{Be}} = DAD_{Be} * CSF_{der_{Be}} \quad (4)$$

where: $CSF_{der\text{-}Be}$ = Cancer slope factor for beryllium for dermal contact based on absorbed dose $(mg/Kg/day)^{-1}$. This dermal cancer slope factor must be calculated from an oral CSF. For constituents that the cancer slope factor is based on an absorbed dose, no adjustment on the oral CSF is needed for the dermal CSF. For those constituents where the oral CSF is based on an administered dose, the dermal slope factor is calculated based the following equation:

$$CSF_{der} = \frac{CSF_{oral}}{GI_{abs}}$$

where: CSF_{oral} = Oral cancer slope factor $(mg/Kg/day)^{-1}$; and
GI_{ABS} = Gastrointestinal absorption factor (unitless).

The oral CSF for beryllium was based on a drinking water study on male rats (ATSDR, 1991), thus an adjustment should be made from an administered to absorbed dose. ECAO recommended a GI_{ABS} of 0.01 for beryllium (memo from Joan Dollarhide to Pat VanLeeuwen, July 21, 1993). Thus, by substituting the oral CSF of 4.3 (EPA [IRIS] 1994) and a GI_{ABS} of 0.01 into Equation 5, a dermal slope factor of 430 is obtained. Therefore, the ILCR from dermal exposure to background concentrations of beryllium in surface soils is calculated as:

$$ILCR_{der_{Be}} = 4.73x10^{-7}\ (mg/Kg/day) * 430\ (mg/Kg/day)^{-1} \quad (6)$$

or:

$$ILCR_{der_{Be}} = 2.03x10^{-4} \quad (7)$$

1.2 Incidental Ingestion from Soil

The ILCR from incidental ingestion of beryllium in surface soil is calculated by first calculating the lifetime average daily intake as follows:

$$I_{ing_{Be}} = \frac{(Cs_{Be})\ (IR)\ (FI)\ (EF)\ (ED)\ (CF)}{(BW)\ (AT)} \quad (8)$$

where: $I_{ing\text{-}Be}$ = Lifetime average daily intake of beryllium from incidental ingestion of surface soil (mg/Kg/day);
IR = Incidental ingestion rate of soil (g/day);
FI = Fraction ingested from the contaminated source (unitless);
EF = Exposure frequency (days/yr);
ED = Exposure duration (years);
CF = Conversion factor (10^{-3} Kg/g);
BW = Body weight (Kg); and
AT = Averaging time (days).

Default values for these parameters are as follows. For illustration purposes, the background concentration for beryllium in surface soils will be used for this example.

$I_{ing\text{-}Be}$ = [calculated below] (mg/Kg/day);
Cs_{Be} = 0.6 mg/Kg [representative background concentration for beryllium in surface soils];
IR = 0.18 g/day [value calculated for the RME farmer, Draft OU1 RI (DOE 1994)];
FI = 1 [assumes 100% exposure to contaminated soils from source];
EF = 350 events/yr [from Risk Assessment Work Plan Addendum (DOE, 1992)];
ED = 70 years [from Risk Assessment Work Plan Addendum (DOE, 1992)];
CF = 10^{-3} Kg/g;
BW = 70 Kg; [default value for adult from Superfund Risk Assessment Guidance (EPA 1989)] and
AT = 25,550 days [default value for assessing incremental lifetime cancer risk from exposure carcinogenic compounds assuming 70 year lifetime from Superfund Risk Assessment Guidance (EPA 1989)].

Substitution of these default parameters into Equation 8 gives an intake rate from incidental ingestion of soil ($I_{ing\text{-}Be}$) as follows:

$$I_{ing_{Be}} = \frac{(0.6\ mg/Kg)\ (0.18\ g/d)\ (1)\ (350\ d/yr)\ (70\ yrs)\ (10^{-3}\ Kg/g)}{(70\ Kg)\ (25{,}550\ d)} \quad (9)$$

or:

$$I_{ing_{Be}} = 1.48x10^{-6} \quad (10)$$

The incremental lifetime cancer risk (ILCR) from exposure to beryllium via incidental ingestion of soil is calculated with the equation:

$$ILCR_{ing_{Be}} = I_{ing_{Be}} * CSF_{oral_{Be}} \quad (11)$$

Substituting the proper values gives:

$$ILCR_{der_{Be}} = 1.48x10^{-6}\ (mg/Kg/day) * 4.3\ (mg/Kg/day)^{-1} \quad (12)$$

or:

$$ILCR_{ing_{Be}} = 6.36x10^{-6} \quad (13)$$

Thus, a concentration of 0.6 mg/Kg of beryllium in surface soils (background) yields an ILCR for dermal contact of 2.03×10^{-4}, an ILCR of 6.36×10^{-6} for incidental ingestion, for a combined total of 2.1×10^{-4}. A comparison of the ILCR from dermal contact to the ILCR from incidental ingestion suggests that the dermal pathway contributes approximately 97% to the total ILCR.

2.0 EXAMPLE CALCULATIONS FOR DERMAL CONTACT AND INCIDENTAL INGESTION OF SOIL BASED ON PROPOSED PARAMETER VALUES

This section presents example calculations for calculating the ILCR from exposure to beryllium in soils using proposed parameter value for the dermal absorption rate for beryllium from soil.

2.1 Dermal Contact with Beryllium in Soil

An incremental lifetime cancer risk from dermal contact with beryllium in soil is calculated using Equation 1. Default values for these parameters are as follows. However, the value for ABS_{Be} was changed from 0.01 (1%) to 0.001 (0.1%), according to an agreement made at a meeting between DOE-FN and EPA-Region V on July 7, 1994. Parameter values used for this calculation are:

DAD_{Be}	=	[calculated below] (mg/Kg/day);
Cs_{Be}	=	0.6 mg/Kg [representative background concentration for beryllium in surface soils];
SA	=	5,750 cm^2/event [25% of 95th percentile value for body surface area of 23,000 cm^2 from Dermal Assessment Guidance, (EPA 1992)];
AF	=	1 mg/cm^2 [maximum of range from 0.2 to 1 from Dermal Assessment Guidance, (EPA 1992)];
ABS_{Be}	=	0.001 (unitless) [proposed value for beryllium from meeting between EPA-Region V and DOE-FN, July 7, 1994];
EF	=	350 events/yr [from Risk Assessment Work Plan Addendum (DOE, 1992)];
ED	=	70 years [from Risk Assessment Work Plan Addendum (DOE, 1992)];
CF	=	10^{-6} Kg/mg;
BW	=	70 Kg; [default value for adult from Superfund Risk Assessment Guidance (EPA 1989)] and
AT	=	25,550 days [default value for assessing incremental lifetime cancer risk from exposure carcinogenic compounds assuming 70 year lifetime from Superfund Risk Assessment Guidance (EPA 1989)].

Substitution of these default parameters into Equation 1 gives a DAD_{Be} as follows:

$$DAD_{Be} = \frac{(0.6\ mg/Kg)\ (5{,}750\ cm^2)\ (1\ mg/cm^2)\ (0.001)\ (350\ d/yr)\ (70\ yrs)\ (10^{-6})}{(70\ Kg)\ (25{,}550\ d)} \quad (14)$$

or:

$$DAD_{Be} = 4.73x10^{-8} \quad (15)$$

The ILCR from exposure to beryllium via dermal contact is calculated with Equation 4. Therefore, by substituting the dermal applied dose from beryllium (DAD_{Be}) and dermal cancer slope factor for beryllium ($CSF_{der\text{-}Be}$) into Equation 4 gives an ILCR from dermal exposure (assuming background concentrations) of:

$$ILCR_{der_{Be}} = 4.73x10^{-8}\ (mg/Kg/day) * 430\ (mg/Kg/day)^{-1} \quad (16)$$

or:

$$ILCR_{der_{Be}} = 2.03x10^{-5} \quad (17)$$

2.2 Incidental Ingestion from Soil

The ILCR from incidental ingestion of beryllium in surface soil is calculated using Equations 8 to 13. DOE-FN is not proposing to use alternative parameter values for incidental ingestion of beryllium

from soil. Thus, the intake of beryllium from background concentration in soil via incidental ingestion is 1.48×10^{-6} with an ILCR of 6.36×10^{-6}.

The concentration of 0.6 mg/Kg of beryllium in surface soils (i.e., background) yields an ILCR for dermal contact of 2.03×10^{-5}, an ILCR of 6.36×10^{-6} for incidental ingestion, for a combined total of 2.7×10^{-5}. A comparison of the ILCR from dermal contact to the ILCR from incidental ingestion suggests that the dermal pathway contributes approximately 76% to the total ILCR using the proposed value of 0.001 for the dermal absorption rate (ABS_{Be}).

3.0 SUMMARY AND CONCLUSIONS

As illustrated by the example calculations using default parameters, the dermal exposure pathway to soil for beryllium is assumed to contribute 97% to the total risk. DOE feels that this conclusion is contradictory to current knowledge regarding beryllium toxicokinetics. ECAOs literature review (memo from Joan Dollarhide to Pat VanLeeuwen, July 21, 1993) clearly states the following points:

1) *"It is unlikely that beryllium is absorbed through intact skin."* (page 54)

2) *"Because of the chemical properties of beryllium, it is unlikely that significant amounts could be absorbed through the skin."* (page 54-55)

Therefore, DOE-FN concludes that the default values proposed by ECAO do not provide results that are consistent current knowledge of beryllium absorption. The use of the proposed value of 0.001 (0.1%) for dermal absorption rate (ABS), which is a default value for metals, although reduces the significance of dermal contact with beryllium, it still appears to overestimate the significance from the dermal exposure pathway. Thus, DOE-FN proposes to evaluate the contribution to the ILCR for beryllium from the dermal exposure pathway from soil by assuming its contribution is equal to that from the oral route (i.e., incidental ingestion) until more definitive data can be obtained for this route of exposure. This method is viewed as conservative considering the carcinogenic effect under consideration are an increased incidence of tumors in male rats from ingestion of beryllium in drinking water. For this effect to occur from dermal contact, absorption across the epidermis would be required.

References

Agency for Toxic Substances and Disease Registry (ATSDR) 1991. "Toxicological Profile for Beryllium." Draft for Public Comment. U.S. Public Health Service, Atlanta, GA.

U.S. Department of Energy (DOE), 1992. "Risk Assessment Work Plan Addendum." Fernald Environmental Management Project, U.S. Dept. of Energy, Fernald Field Office, Fernald OH.

U.S. Department of Energy (DOE), 1994. "Remedial Investigation Report for Operable Unit 1." Fernald Environmental Management Project, U.S. Dept. of Energy, Fernald Field Office, Fernald OH.

U.S. Environmental Protection Agency (EPA), 1989, "Risk Assessment Guidance for Superfund: Human Health Evaluation Manual Part A, Interim Final." EPA/540/1-89/002. EPA, Office of Emergency and Remedial Response, Washington, D.C.

U.S. Environmental Protection Agency (EPA), 1992, "Dermal Exposure Assessment: Principles and Applications." EPA/600/8-91/011B. EPA, Office of Research and Development, Washington, D.C.

U.S. Environmental Protection Agency (EPA), 1993, Memorandum from Joan Dollarhide, ECAO, to Pat VanLeeuwan, EPA Region V, July 21, 1993.

U.S. Environmental Protection Agency (EPA), 1994, "Integrated Risk Information System (IRIS)." computer database, EPA, Washington, D.C.

ATTACHMENT 6
SUMMARY OF RISK-BASED PRELIMINARY REMEDIATION GOALS FOR BERYLLIUM IN SOIL

F - 17312

SUMMARY OF RISK-BASED PRELIMINARY REMEDIATION GOALS FOR BERYLLIUM IN SOIL[a,b]

		Carcinogenic Effects			Systemic Toxicity
Land Use Scenario	Receptor / Risk Level=	10^{-6} (mg/Kg)	10^{-5} (mg/Kg)	10^{-4} (mg/Kg)	HI=0.2 (mg/Kg)
Agricultural	RME Farmer	0.048	0.48	4.8	NA
	Child	NA	NA	NA	55
	CT Farmer	0.98	9.8	98	540
	Consumer Meat/Milk	0.22	2.2	22	970
Commercial/Industrial	Groundskeeper	0.42	43.2	42	650
Recreational	Developed Park	0.97	9.7	97	4,200
	Undeveloped Park	1.5	15	150	6,500
	Wildlife Reserve	1.8	18	180	7,900
Government Reserve	Trespassing Youth	6.7	67	670	4,900
	Expanded Trespasser	2.1	21	210	5,700

Notes:

[a]Supplemental Guidance to the Risk Assessment Work Plan Addendum (Supplement No. 94-013) states that oral dose-response factors should be used, without adjustment, for assessing risk from dermal exposure pathway

[b]Assumes a particulate dust concentration of 2×10^{-5} g/m^3, the default value for Operable Unit 5.

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SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

SPECIATION OF TOTAL CHROMIUM IN SURFACE SOIL

SUPPLEMENT NO. 94-014
REVISION NO. 0

AUGUST 29, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000134

RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
08/19/94	0	Provides guidance for establishing the speciation of chromium in surface soils at the Fernald site.

1.0 OBJECTIVE

This policy provides guidance for establishing the speciation of chromium in surface soils at the Fernald Environmental Management Project (FEMP). This information is necessary for the evaluation of potential risks from exposure to chromium present in site surface soils.

2.0 SUPPLEMENTAL GUIDANCE

As a result of sampling and analysis of representative surface soils, risk assessment efforts at the FEMP should assume a range of values from 1 to 10 percent hexavalent chromium (chromium VI), the carcinogenic species, for total measured chromium. The remaining percent (90 to 99 percent) is assumed to be trivalent chromium (chromium III), the noncarcinogenic species. This value is conservative when compared to actual sampling results and represents a site-specific assumption that will be protective of human health and the environment.

3.0 SUPPORTING INFORMATION

Soil demonstrating levels of total chromium elevated above regional background levels has been detected at the FEMP. The particular form of chromium present is an important issue for risk assessments because chromium VI is a hazardous oxidation state of chromium due to its toxicity, carcinogenicity, and mobility. Small concentrations of chromium VI can be much more significant than high levels of chromium III due to its carcinogenicity.

Unlike chromium III, chromium VI is a known human carcinogen. Occupational epidemiologic studies of chromium-exposed workers are consistent across study populations and show that dose-response relationships have been established for chromium exposure and lung cancer. There are no long-term studies of ingested chromium VI in humans (U.S. Department of Health Services 1991). In contrast, chromium III is an essential trace nutrient participating in glucose and cholesterol metabolism.

The inhalation cancer slope factor obtained from the Integrated Risk Information System (IRIS) (EPA 1993) for chromium VI is 42 milligrams per kilogram per day $(mg/kg/day)^{-1}$, which is based upon a unit risk factor of 0.012 micrograms per cubic meter (ug/m^3). Chromium VI is also significantly more toxic than chromium III. The oral reference dose for chromium VI is 0.005 mg/kg/day. This is 200 times lower than the 1mg/kg/day reference dose for chromium III.

When estimating risk posed to potential human receptors due to chromium exposure from solid matrices such as soil or waste, it is necessary to determine the proportion of chromium III to chromium IV chromium present at the exposure point(s) for the receptor(s) undergoing evaluation.

Standard analytical investigations conducted on solid matrices usually report "total chromium" concentration but do not routinely analyze for the proportion of chromium VI in relation to total chromium or chromium III. Without information regarding the speciation of chromium in the soil/waste being evaluated, risk calculations routinely assume that 100 percent of the total chromium detected exists in the more toxic hexavalent state. Use of this assumption may result in considerable overestimation of potential risks associated with exposure to chromium.

Surface soil sampling and analysis was conducted at the FEMP to obtain site-specific information to address this issue. Approximately 20 surface soil samples were collected from Operable Unit 1 and analyzed for both total chromium and chromium VI (Table 1). The Operable Unit 1 area was chosen for representative sampling due to consistent detects of chromium which were relatively high in comparison to chromium detects noted elsewhere at the site. The concentrations of total chromium and chromium VI in soil were determined using EPA SW-846 method 3060, "Alkaline Digestion," and method 7195, "Co-precipitation". The results are presented in Table 1 and indicate that chromium VI contributed less than 1.5 percent of the total chromium detected in the representative soil samples obtained from the site.

Environmental transformation of chromium species is dominated by the cycling of chromium III and chromium VI via reduction-oxidation reactions. Subsequent interactions and reactions in the environment are related to the physical or chemical properties of the reduced (chromium III) or oxidized (chromium VI) species. Chromium III compounds are hydrolyzed readily to form insoluble compounds such as chromium hydroxides [$Cr(OH)_3$]; thus, precipitation and dissolution are the predominant reactions affecting levels of chromium III in soils. Chromium VI exists mostly as an ionic chromate (CrO_{4-2}) and bichromate ($HCrO_4^-$) in alkaline soils. As an ionic compound, the most important reactions affecting chromium VI levels in soil are adsorption and desorption. Therefore, chromium VI can be much more mobile in soils than chromium III, especially in soils with high pH levels. The reduction of chromium VI is enhanced by low pH (Cary 1982). In most surface soils, chromium will be present predominantly in the form of chromium III.

TABLE 1
SPECIATION OF CHROMIUM IN SURFACE SOIL
SUMMARY OF ANALYTICAL RESULTS

Sampling Location	Total Cr (mg/Kg)	Cr VI[a] (mg/Kg)	Cr VI Qualifier	Percent Cr VI	Cr VI[b] (mg/Kg)	Percent Cr VI[c]
SP-1	14.3	0.067		0.47	0.067	0.47
SP-2	13.9	0.07		0.50	0.07	0.50
SP-3	13	0.07		0.54	0.07	0.54
SP-3A	10	0.07		0.70	0.07	0.70
SP-4	8.43	0.06	U	0.71	0.03	0.36
SP-5	7.31	0.06	U	0.82	0.03	0.41
SP-6	8.1	0.06	U	0.74	0.03	0.37
SP-7	4.4	0.06	U	1.36	0.03	0.68
SP-8	5.29	0.06	U	1.13	0.03	0.57
SP-9	8.43	0.06	U	0.71	0.03	0.36
SP-10	5.94	0.06	U	1.01	0.03	0.51
SP-11	6.11	0.06	U	0.98	0.03	0.49
SP-12	9.35	0.067		0.72	0.067	0.72
SP-13	6.61	0.06	U	0.91	0.03	0.45
SP-14	6.9	0.06	U	0.87	0.03	0.43
SP-15	6.91	0.06	U	0.87	0.03	0.43
SP-16	9.45	0.06		0.63	0.06	0.63
SP-17	4.57	0.06	U	1.31	0.03	0.66
SP-18	6.63	0.06	U	0.90	0.03	0.45
SP-19	5.42	0.08		1.48	0.08	1.48
SP-20	4.21	0.06	U	1.43	0.03	0.71
		Average		0.895 %		0.568%
		STD		0.30		
		UCL		1.39 %		

Total Cr = total chromium
Cr VI = hexavalent chromium
U = undetects for hexavalent chromium in sample
STD = standard deviation
UCL = upper confidence limit – 95 percentile
[a] Values for undetected hexavalent chromium samples include the detection limit.
[b] Values for hexavalent chromium include half the detection limit for undetected samples.
[c] Percentages were calculated using half the Cr VI detection limit for undetected samples.

4.0 REFERENCES

Bartlett, R. James, B. al. 1979, "Behavior of Chromium in Soils," Journal of Environmental Quality, Vol. 8 No. 1.

Cary, E.E., 1982, "Chromium in Air, Soil and Nature," Topics in Environmental Health 5: Biological and Environmental Aspects of Chromium, S. Langard, ed., Elsevier Science Publisher, New York, NY, pp. 49-64.

U.S. Department of Health and Human Services, 1991, "Toxicological Profile for Chromium," Agency for Toxic Substances and Disease Registry, October 1991.

U.S. Environmental Protection Agency, 1994, "Integrated Risk Information System (IRIS)", on-line date service, U.S. EPA, Washington, DC.

F-7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

SOIL INGESTION RATES FOR THE RME AND CT FARMER

SUPPLEMENT NO. 94-015
REVISION NO. 0

AUGUST 29, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000140

Title: Soil Ingestion Rates for the RME and CT Farmer	P = 7312
SUPPLEMENT NO. 94-015 REVISION NO. 0	
Effective Date: August 29, 1994	Page 1 of 6

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0001 1

RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
08/19/94	0	Text and documentation to be used for the soil ingestion rates for the RME and CT farmer.

1.0 OBJECTIVE

At a meeting between the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) on July 7, 1994, to discuss and resolve comment responses to the Operable Unit 1 Remedial Investigation (RI) report, verbal agreement was received from EPA Region V on several issues pertaining to risk assessments at the FEMP. The soil ingestion rate used for the reasonable maximum exposure (RME) and central tendency (CT) farmers was one of the issues resolved. In general, EPA agreed upon the soil ingestion rates presently being used in the FEMP risk assessment calculations. However, EPA stated they would like the supporting text for these parameters to clearly indicate that these parameters are assumptions and to no longer reference the Operable Unit 4 RI report as the source of these parameters.

This guidance provides the text to be used for describing both the soil ingestion rates and the outdoor exposure times for the CT and RME farmers to be used in risk assessment calculations at the FEMP.

2.0 SUPPLEMENTAL GUIDANCE

The following text and table will be used in future risk assessments to support and document the derivation of the soil ingestion rates used for the RME and CT farmers. This text was taken from the change pages submitted with the Operable Unit 1 RI comment response document. The changed text corresponds with original comment number 11(40) from Pat Van Leeuwen (EPA) and has received verbal approval from EPA Region V.

> "The literature was consulted to determine an appropriate soil incidental ingestion rate for a farmer. However, no default values were found. Therefore, this value was estimated assuming the following:
>
> - Soil ingestion rate on days while tilling, plowing, planting or harvesting would assume a higher average daily value of 0.48 g/day from EPA default exposure assumptions (EPA 1991).
> - For all other activities, an average daily soil ingestion rate of 0.1 g/day will be used.
>
> To determine the amount of time a farmer is engaged in the described activities, a review of farming parameters (farm size and crop configuration) were conducted for Hamilton County. The 1987 Census of Agriculture (U.S. Department of Commerce 1989) indicates that 1,284 of the 1,364 farms in Hamilton and Butler counties (95 percent) are under 500 acres (5 percent are 500 acres or above). Therefore, 500 acres was selected as the RME farm size. The soil ingestion rate for the CT farmer was based on similar farm configuration but using an average (CT) farm size of 125 acres (U.S. Department of Agriculture 1976; 1979). To determine the times associated with farming, a farmer was assumed to follow recommended agricultural practices for the region. A farmer is assumed to rotate this crops and plant 35 percent (175 acres) in corn, 35 percent in soybeans, 20 percent (100 acres) in wheat, and 10 percent (50 acres) in hay. It must be acknowledged that this configuration is a typical configuration and may represent an average value because each crop has a different time associated with field preparation,

planting, and harvesting. However, data is not available to determine a RME configuration. Therefore, an alternative configuration could result in a slightly higher or slightly lower exposure. The RME farm size of 500 acres was assumed to be adequate to compensate for this uncertainty.

Table 1 presents the detailed calculations for soil ingestion rate for the RME and CT farmers. The U.S. Soil Conservation Service Field Technical Guide (U.S. Department of Agriculture 1992) indicates that a farmer spends about 1.24 hours per acre farming corn, 1 hour per acre farming soybeans, 1.28 hours per acre farming wheat, and 2.73 hours per acre farming hay. Assuming the farm configuration described above, an RME farmer would spend approximately 660 hours farming (plowing, discing, planting, and/or harvesting). An additional 20 percent is added to this time to account for miscellaneous activities and the uncertainty with the farm configuration described above to give a total of 800 hours or 100 working days. Therefore, it is assumed that a farmer would incidentally ingest 0.48 g/day of soil for 100 days per year spent tilling the soil and 0.1 g/day for the remaining 250 days per year. This results in a combined average ingestion rate of 0.18 grams/day for 350 days per year, assuming an average (CT) farmer has a soil ingestion rate of 0.120 g/day."

The text provided below should be used in future FEMP risk assessments to describe and document the derivation of the external exposure times for the RME and CT farmer receptors.

"The total gamma exposure time assumed for the on-property RME farmer is 24 hours per day, 350 days per year, for 70 years. However, the exposure time per day was divided into two exposure times: exposure time outdoors (ET_{out}), which assumes no shielding factor, and exposure time indoors (ET_{in}), which assumes a shielding factor of 0.5.

The RME adult farmer scenarios constructed for this profile assume the receptor works outside of the residence for 2000 hours per year. Spreading this time over the 350 days per year of on-site exposure yields an average outdoor exposure time of 5.7 hours per day. This leaves an indoor exposure time of 18.3 hours per day for this receptor. Thus, about 25 percent of the receptor's time on site is spent outside of the residence. These values apply to both the off-property RME resident adult farmer and the on-property RME resident adult farmer. The on-property RME resident child is assumed to spend only 2 hours per day outdoors, for a total of 700 hours per year.

It is assumed that the CT resident adult farmer is exposed outdoors for 1,152 hours (equal to 48 days of continuous exposure) out of the 275 days spent within the boundaries of the operable unit each year (EPA 1993). This is equivalent to an average exposure time of 4.2 hours per day. It is assumed that the CT resident adult farmer is exposed outdoors for 275 days per year, which is equivalent to 1155 hours of outdoor exposure in a year. This leaves an indoor exposure time of 19.8 hours per day for this receptor. Thus, about 20 percent of the receptor's time on site is spent outside of the residence. These values apply only to the CT receptor."

TABLE 1
CALCULATION OF SOIL INGESTION RATE FOR RME AND CT FARMER

	RME Farmer		CT Farmer	
Farm Size (acres)	500 RME farm size (95th percentile)		125 CT farm size (50th percentile)	
Acreage in corn	175 acres	35%	44 acres	35%
Acreage in soybeans	175 acres	35%	44 acres	35%
Acreage in wheat	100 acres	20%	25 acres	20%
Acreage in hay	50 acres	10%	13 acres	10%
Hours farming corn	217 hrs/yr	1.24 hrs/acre	54 hrs/yr	1.24 hrs/acre
Hours farming soybeans	175 hrs/yr	1 hrs/acre	44 hrs/yr	1 hrs/acre
Hours farming wheat	128 hrs/yr	1.28 hrs/acre	32 hrs/yr	1.28 hrs/acre
Hours farming hay	136.5 hrs/yr	2.73 hrs/acre	34 hrs/yr	2.73 hrs/acre
TOTAL:	656.5 hrs/yr		164 hrs/yr	
Hours Farming (Total + 20%)	800 hours		200 hours	
Days spent farming	100 days/yr		25 days/yr	
Years farming	50 years		50 years	
Ingestion rate while farming	0.48 g/day		0.48 g/day	
Soil Ingestion farming	2400 g		600 g	
Days not farming	250 days/yr		325 days/yr	
Years farming	50 years		50 years	
Ingestion rate for adult	0.1 g/day		0.1 g/day	
Soil Ingestion not farming	1250 g		1625 g	
Days for child	350 days/yr		350 days/yr	
Years as a child	6 years		6 years	
Ingest rate for child	0.2 g/day		0.2 g/day	
Soil Ingestion for child	420 g		420 g	
Days per year	350 days/yr		350 days/yr	
Years not farming	14 years		14 years	
Ingest rate for adult	0.1 g/day		0.1 g/day	
Soil Ingestion – not farming	490 g		490 g	
Soil ingestion over a lifetime	4560 g/lifetime		3135 g/lifetime	
Avg. Daily Soil Ingest. Rate	0.18 g/day		0.12 g/day	

3.0 SUPPORTING INFORMATION

None

4.0 REFERENCES

U.S. Department of Commerce, 1989, "Census of Agriculture, Geographic Area Series, Part 35, Ohio, State and County Data," Bureau of the Census, Washington, DC.

U.S. Department of Agriculture, 1992, "Revised Field Office Technical Guide," Soil Conservation Service, Cincinnati, OH.

U.S. Department of Agriculture, 1979, "Soil Survey of Hamilton County, Ohio," Soil Conservation Service, Cincinnati, OH.

U.S. Department of Agriculture, 1976, "Soil Survey of Butler County, Ohio," Soil Conservation Service, Hamilton, OH.

U.S. Environmental Protection Agency, 1991, "Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors," OSWER Directive 9285.6-03, Office of Emergency and Remedial Response, Washington, DC.

U.S. Environmental Protection Agency, 1993, "Superfund Standard Default Exposure Factors for Central Tendency and Reasonable Maximum Exposure," Preliminary Draft, May 5, 1993.

F-7312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

SIGNIFICANT FIGURES GUIDANCE FOR RISK CALCULATIONS

SUPPLEMENT NO. 94-016
REVISION NO. 0

AUGUST 29, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD FIELD OFFICE

000147

Title: Significant Figures Guidance for Risk Calculations	F-7312
SUPPLEMENT NO. 94-016 REVISION NO. 0	
Effective Date: August 29, 1994	Page 1 of 4

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Title: Significant Figures Guidance for Risk Calculations		E-8312
SUPPLEMENT NO. 94-016 REVISION NO. 0		
Effective Date: August 29, 1994	Page 2 of 4	

RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
08/19/94	0	Provides guidance on the required amount of significant figures for risk calculations at the FEMP

1.0 OBJECTIVE

This guidance defines the required number of significant figures agreed upon by the U.S. Department of Energy (DOE) and the U.S. Environmental Protection Agency (EPA) for presenting risk calculations in remedial investigation/feasibility study (RI/FS) and Comprehensive Response Action Risk Evaluation (CRARE) reports submitted to the regulatory agencies.

2.0 SUPPLEMENTAL GUIDANCE

All risk calculations presented for both hazard index (HI) and incremental lifetime cancer risk (ILCR) in summary tables will be presented to two significant figures. All detailed risk calculations presented in supporting data tables (i.e., attachments) must be presented to at least two (i.e., two or more) significant figures. The following examples present summary tables using two significant figures and demonstrate that the totals in the summary table may be slightly higher or lower than the results of the supporting data.

Example 1:

SUPPORTING DATA

	VALIDATED RESULTS
TOXICANT A	1.236
TOXICANT B	0.604
TOXICANT C	9.513
TOTAL HI	11.353

SUMMARY TABLE

	RECEPTOR HQ
TOXICANT A	1.2
TOXICANT B	0.60
TOXICANT C	9.5
TOTAL HI	11

EXAMPLE 2: Supporting Data

SUPPORTING DATA

	VALIDATED RESULT RECEPTOR A	VALIDATED RESULT RECEPTOR B
CARCINOGEN A	3.42×10^{-6}	4.41×10^{-5}
CARCINOGEN B	2.54×10^{-6}	2.23×10^{-6}
CARCINOGEN C	1.66×10^{-6}	4.51×10^{-6}
TOTAL ILCR	7.62×10^{-6}	5.084×10^{-5}

SUMMARY TABLE

	RECEPTOR A*	RECEPTOR B
CARCINOGEN A	3.4×10^{-6}	4.4×10^{-5}
CARCINOGEN B	2.5×10^{-6}	2.2×10^{-6}
CARCINOGEN C	1.6×10^{-6}	4.5×10^{-6}
TOTAL ILCR	7.6×10^{-6}	5.1×10^{-5}

*The rounding can result in a discrepancy between values presented in the summary table(s) and values resulting from detailed calculations. These potential discrepancies are acceptable in this context.

3.0 **SUPPORTING INFORMATION**

This policy is based on final comment resolution between EPA and DOE concerning risk calculations in the Draft Final Operable Unit 1 RI report (dated February 1994)

4.0 **REFERENCES**

U.S. Department of Energy, "Draft Final Operable Unit 1 Remedial Investigation Report," FEMP, Remedial Investigation and Feasibility Study, Fernald, OH, DOE, Fernald Field Office, Fernald, OH.

F-27312

SUPPLEMENTAL GUIDANCE TO THE

RISK ASSESSMENT WORK PLAN ADDENDUM

JUNE 1992

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT
FERNALD, OHIO

USE OF THE RISK RANGE CONCEPT WHEN CONSIDERING MULTIPLE COCS IN THE OPERABLE UNIT 5 FEASIBILITY STUDY

SUPPLEMENT NO. 94-017
REVISION NO. 0

NOVEMBER 30, 1994

U.S. DEPARTMENT OF ENERGY
FERNALD AREA OFFICE

000152

Title: Use of the Risk Range Concept When Considering Multiple COCs in the Operable Unit 5 Feasibility Study	
SUPPLEMENT NO. 94-017 REVISION NO. 0	A = 7312
Effective Date: November 30, 1994	Page 1 of 5

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SUPPLEMENT NO. 94-017 REVISION NO. 0	f-17312
Effective Date: November 30, 1994	Page 2 of 5

RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION
11/30/94	0	Provides guidance on the approach to account for potential multiple COCs when determining risk impacts.

1.0 OBJECTIVE

The National Contingency Plan of 1990 (NCP) [40 C.F.R. Part 300 (EPA 1990)] states that preliminary remediation goals (PRGs) are to be developed and evaluated for the receptor- specific incremental lifetime cancer risk (ILCR) range of 10^{-4} to 10^{-6}. This "target risk range" is used when evaluating selected land use alternatives in the FS and is discussed in the Supplemental Guidance to the Risk Assessment Work Plan Addendum (RAWPA), Number 94-009.

Tiered order-of-magnitude risk levels are established for individual constituents of concern (COCs). At many Superfund sites, multiple COCs exist; additionally, within the U.S. Department of Energy (DOE) weapons complex, mixed waste (the presence of both radiological and chemical contaminants) is prevalent. To evaluate the presence of multiple COCs and remain within the regulatory framework that directs cleanups, a consistent approach is required to account for potential multiple COC risk impacts.

2.0 SUPPLEMENTAL GUIDANCE

Utilizing information generated in a operable unit-specific baseline risk assessment, a comprehensive COC list is prepared for the COCs attributable to the operable unit according to Supplemental Guidance to the RAWPA, Number 94-002. After exposure point concentrations are calculated for COCs in relevant pathways, risk quantification is conducted on target receptors and reference receptors are selected for consistency with projected future land use of the operable unit.

Risks attributable to individual COCs are then added numerically to yield combined total ILCR and hazard index (HI) risks to the target receptors. For the purposes of conducting a feasibility study (FS), a method must be defined that will:

- eliminate contaminants that have been defined as constituents of potential concern (CPCs)/COCs but do not contribute significantly to risk.
- reduce the number of constituents on CPC/COC list while retaining all of the significant contaminants that need to be addressed in the cleanup.
- prioritize contaminants for the purpose of remediation planning and strategy.
- establish a method of quantifying risk attributable to residuals and determine a maximum potential risk range to target receptors in the post-remedial phase of the cleanup.

3.0 SUPPORTING INFORMATION

The following are ten steps to determine the maximum potential risk range from the impact of multiple COCs in the FS process:

1. Develop a comprehensive list of operable unit-specific COCs per the Supplemental Guidance to the RAWPA, Number 94-002.
2. In the operable unit-specific baseline risk assessment, risks are calculated for a set of evaluated receptors. These hypothetical receptors should be adequate in number to represent the entire range of possible

land uses on the site. Receptors used in the remedial investigation (RI)/FS process at the FEMP are defined and their parameters are described in the Supplemental Guidance to the RAWPA, Numbers 94-006 and 94-008.

3. For each receptor evaluated in the context of the RI baseline risk assessment, risk-based PRGs are developed for each COC in considered media types at 10^{-4}, 10^{-5}, and 10^{-6} ILCR risk levels as required by the NCP. Standard practice has been to simultaneously evaluate an HI of .2 concurrently with these three ILCR levels. The HI value will supersede one or more ILCR risk level(s) if this value is more protective.

4. Using the risk-based PRGs as a starting point, modifications are considered to these values by influencing factors such as cross-media impacts, applicable relevant and appropriate requirements (ARARs), and other site specific factors as described in the Supplemental Guidance to the RAWPA, Number 94-009. The goal of PRG/PRL development in the FS process is to derive cleanup standards for all established COCs that are protective of human health and the environment.

5. A subset of the total number of receptors evaluated in the baseline risk assessment is designated as representing projected land use objectives in the FS. Target on-site receptors may represent activities such as residential/farming, commercial/industrial, recreational, and trespassing. The sole target off-site receptor scenario evaluated for the Fernald Environmental Management Project (FEMP) is residential/farming due to the current agricultural environment surrounding the site.

6. Major risk drivers are determined for the target receptors chosen to represent land use objectives in the FS. This is done by returning to the respective RI baseline risk assessment and selecting the list of COCs responsible for 95 percent of the calculated risk for each target receptor that is designated in the FS alternatives. This is accomplished separately for carcinogens (ILCR) and toxicants (HI).

7. All of the COCs defined in this manner are compiled into lists of 95 percent risk drivers for each target receptor. These receptor-specific 95 percent risk driver lists are then pooled into a master list of 95 percent drivers for all key receptors designated in the FS. Due to the probable additivity of COCs across receptors, this master 95 percent list will normally incorporate COCs that are responsible for more than 95 percent of the risk for any individual receptor and exclude, for purposes of this evaluation, numerous COCs that are responsible for little or no risk to target receptors evaluated in the context of the operable unit FS.

8. PRLs are established for each COC equating to a projected maximum risk level that will be considered for target receptor(s). If the projected risk level is established at 10^{-5}, then by design, every COC will have a <u>maximum potential risk level</u> which will not exceed 1×10^{-5} assuming the

exposure point concentrations do not exceed the PRL. In fact, a PRL is meant to be used as an upper limit of the contaminant in the residual media, not an average concentration. Average concentrations of contaminant in each media will be determined by density and distribution of analytical data and other statistical considerations.

9. When the list of major risk drivers is finalized, it can be used to establish a "maximum potential risk range" of multiple COCs using developed PRGs/PRLs. This can be viewed as the maximum theoretical residual risk value for FS alternative development.

10. By summing the risks of individual COCs on the master 95 percent risk driver list and adding 5 percent to the total value to compensate for the remaining 5 percent, a maximum potential risk range to target receptors can be derived which should be within the 10^{-4} risk range (depending on site specific conditions) as stipulated in Office of Solid Waste and Emergency Response (OSWER) Directive No. 9355.0-30. A generic example is given in Attachment 1.

4.0 REFERENCES

U.S. Environmental Protection Agency, 1990, "National Oil and Hazardous Substance Pollution Contingency Plan; Final Rule," 40 C.F.R., Part 300.

ATTACHMENT 1

MASTER LIST OF 95 PERCENT RISK DRIVERS

	PRG @ 10^{-5}*
COC A	$1X10^{-5}$
COC B	$1X10^{-5}$
COC C	$1X10^{-5}$
COC D	$1X10^{-5}$
COC E	$1X10^{-5}$
COC F	$1X10^{-5}$
COC G	$1X10^{-5}$
COC H	$1X10^{-5}$
COC I	$1X10^{-5}$
COC J	$1X10^{-5}$
COC K	$1X10^{-5}$
COC L	$1X10^{-5}$
COC M	$1X10^{-5}$
COC N	$1X10^{-5}$
COC O	$1X10^{-5}$
COC P	$1X10^{-5}$

Sum of 16 COCs @ $1x10^{-5}$ ILCR	$1.60x10^{-4}$ ILCR
add 5 percent to adjust for 95 percent	$0.08x10^{-4}$ ILCR
MAXIMUM POTENTIAL RISK RANGE	**$1.68x10^{-4}$ ILCR****

* Because $1x10^{-5}$ is a maximum risk level reflected by the PRG and is a "not to exceed" value, the actual maximum would be less (e.g., no greater than $9.9x10^{-6}$).

** This is the maximum potential risk range that could not be exceeded under the FS scenario. The actual calculated risk would prove to be lower due to factors described above. In order to be considered within the acceptable risk range, this maximum potential risk value should not transcend the $4x10^{-4}$ ILCR stipulated in OSWER Directive 9355.0-30 (Attachment 2).

ATTACHMENT 2

PB91-921359

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

APR 22 1991

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER DIRECTIVE 9355.0-30

MEMORANDUM

SUBJECT: Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions

FROM: Don R. Clay
Assistant Administrator

TO: Directors, Waste Management Division
Regions I, IV, V, VII, VIII
Director, Emergency and Remedial Response Division
Region II
Directors, Hazardous Waste Management Division
Regions III, VI, IX
Director, Hazardous Waste Division,
Region X

Purpose

The purpose of this memorandum is to clarify the role of the baseline risk assessment in developing Superfund remedial alternatives and supporting risk management decisions.

Specifically, the following points are made in the memorandum:

- Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted.

- Other chemical-specific ARARs may also be used to determine whether a site warrants remediation.

- A risk manager may also decide that a baseline risk level less than 10^{-4} is unacceptable due to site specific reasons and that remedial action is warranted.

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- Compliance with a chemical-specific ARAR generally will be considered protective even if it is outside the risk range (unless there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure).

- The upper boundary of the risk range is not a discrete line at 1 x 10^{-6}, although EPA generally uses 1 x 10^{-6} in making risk management decisions. A specific risk estimate around 10^{-6} may be considered acceptable if justified based on site-specific conditions.

- The ROD should clearly justify the use of any non-standard exposure factors and the need for remedial action if baseline risks are within the generally acceptable risk range. The ROD should also include a table listing the final remediation goals and the corresponding risk level for each chemical of concern.

Background

The 1990 National Contingency Plan (NCP) (55 Fed. Reg. 8665-8865 (Mar. 8, 1990)) calls for a site-specific baseline risk assessment to be conducted, as appropriate, as part of the remedial investigation (Section 300.430(d)(1)). Specifically, the NCP states that the baseline risk assessment should "characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain" (Section 300.430(d)(4)). The primary purpose of the baseline risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health and the environment posed by the site and any uncertainties associated with the assessment. This information may be useful in determining whether a current or potential threat to human health or the environment exists that warrants remedial action.

The "Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual - Part A" (HHEM) (EPA/540/1-89/002) provides guidance on how to conduct the human health portion of the baseline risk assessment. Volume II of the "Risk Assessment Guidance for Superfund" the "Environmental Evaluation Manual" (EPA/540/1-89/001) and the companion manual, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference" (EPA/600/3-89/013) provide guidance on conducting the environmental portion of the baseline risk assessment. Other pertinent guidance includes the "Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA" (RI/FS guidance, EPA/540/G-89/004), which describes how the baseline risk assessment fits into the overall RI/FS process. "Guidance on Preparing Superfund Decision Documents" (ROD guidance)

(EPA/624/1-87/001) provides information on how to document the results of the baseline risk assessment in the ROD.

Objective

The objective of this memorandum is to provide further guidance on how to use the baseline risk assessment to make risk management decisions such as determining whether remedial action under CERCLA Sections 104 or 106 is necessary. This memorandum also clarifies the use of the baseline risk assessment in selecting appropriate remedies under CERCLA Section 121, promotes consistency in preparing site-specific risk assessments, and helps ensure that appropriate documentation from the baseline risk assessment is included in Superfund remedy selection documents.

Implementation

RISKS WARRANTING REMEDIAL ACTION

Whenever there is a release or substantial threat of release of a hazardous substance into the environment (or a release or threat of release into the environment of a pollutant or contaminant "which may present an imminent and substantial danger to public health or welfare"), Section 104(a)(1) of CERCLA provides EPA with the authority to take any response action consistent with the National Contingency Plan it deems necessary to protect public health or welfare or the environment. Section 106 of CERCLA grants EPA the authority to require potentially responsible parties (or others) to perform removal or remedial actions "when the President determines that there may be an imminent and substantial endangerment to the public health or welfare or the environment because of an actual or threatened release of a hazardous substance from a facility."

As a general policy and in order to operate a unified Superfund program, EPA generally uses the results of the baseline risk assessment to establish the basis for taking a remedial action using either Section 104 or 106 authority. EPA may use the results of the baseline risk assessments to determine whether a release or threatened release poses an unacceptable risk to human health or the environment that warrants remedial action and to determine if a site presents an imminent and substantial endangerment. The risk assessment methodology for all sites should be the same regardless of whether the RI/FS or remedial design and remedial action is performed by EPA or potentially responsible parties.

Generally, where the baseline risk assessment indicates that a cumulative site risk to an individual using reasonable maximum exposure assumptions for either current or future land use exceeds the 10^{-4} lifetime excess cancer risk end of the risk

range, action under CERCLA is generally warranted at the site. For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, action generally is not warranted, but may be warranted if a chemical specific standard that defines acceptable risk is violated or unless there are noncarcinogenic effects or an adverse environmental impact that warrants action. A risk manager may also decide that a lower level of risk to human health is unacceptable and that remedial action is warranted where, for example, there are uncertainties in the risk assessment results. Records of Decision for remedial actions taken at sites posing risks within the 10^{-4} to 10^{-6} risk range must explain why remedial action is warranted.

The cumulative site baseline risk should include all media that the reasonable maximum exposure scenario indicates are appropriate to combine and should not assume that institutional controls or fences will account for risk reduction. For noncarcinogenic effects of toxicants, unacceptable risk occurs when exposures exceed levels which represent concentrations to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, as appropriate to address teratogenic and developmental effects.

Chemical specific standards that define acceptable risk levels (e.g., non-zero MCLGs, MCLs) also may be used to determine whether an exposure is associated with an unacceptable risk to human health or the environment and whether remedial action under Section 104 or 106 is warranted. For ground water actions, MCLs and non-zero MCLGs will generally be used to gauge whether remedial action is warranted.

EPA uses the general 10^{-4} to 10^{-6} risk range as a "target range" within which the Agency strives to manage risks as part of a Superfund cleanup. Once a decision has been made to take an action, the Agency has expressed a preference for cleanups achieving the more protective end of the range (i.e., 10^{-6}), although waste management strategies achieving reductions in site risks anywhere within the risk range may be deemed acceptable by the EPA risk manager. Furthermore, the upper boundary of the risk range is not a discrete line at 1×10^{-4}, although EPA generally uses 1×10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if justified based on site-specific conditions, including any remaining uncertainties on the nature and extent of contamination and associated risks. Therefore, in certain cases EPA may consider risk estimates slightly greater than 1×10^{-4} to be protective.

When an ARAR for a specific chemical (or in some cases a group of chemicals) defines an acceptable level of exposure,

compliance with the ARAR will generally be considered protective even if it is outside the risk range (unless there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure). Conversely, in certain situations EPA may determine that risks less than 1×10^{-6} are not sufficiently protective and warrant remedial action.

Where current conditions have not resulted in a release posing risks that warrant action but there is a significant possibility that a release will occur that is likely to result in an unacceptable risk, remedial action may also be taken. The significance of the potential future release may be evaluated in part based on the quantities of material at the site and the environmental setting.

RISKS CONSIDERED IN RISK MANAGEMENT DECISION

As noted above, both current and reasonably likely future risks need to be considered in order to demonstrate that a site does not present an unacceptable risk to human health and the environment. An adequate consideration of future risk may necessitate the assessment of risks assuming a land use different from that which currently exists at the site. The potential land use associated with the highest level of exposure and risk that can reasonably be expected to occur should be addressed in the baseline risk assessment. Further, this land use and these exposure assumptions should be used in developing remediation goals.

The preamble to the NCP states that EPA will consider future land use as residential in many cases. In general, residential areas should be assumed to remain residential; and undeveloped areas can be assumed to be residential in the future unless sites are in areas where residential land use is unreasonable. Often the exposure scenarios based on potential future residential land use provide the greatest risk estimates (e.g., reasonable maximum exposure scenario) and are important considerations in deciding whether to take action (55 Fed. Reg. at 8710).

However, the NCP also states that "the assumption of future residential land use may not be justifiable if the probability that the site will support residential use in the future is small." Sites that are surrounded by operating industrial facilities can be assumed to remain as industrial areas unless there is an indication that this is not appropriate. Other land uses, such as recreational or agricultural, may be used, if appropriate. When exposures based on reasonable future land use are used to estimate risk, the NCP preamble states that the RCO "should include a qualitative assessment of the likelihood that the assumed future land use will occur" (55 Fed. Reg. at 8710).

Unacceptable environmental risks also may prompt remedial action and may occur where there is no significant risk to human health. Threats or potential threats to sensitive habitats, such as wetlands, and critical habitats of species protected under the Endangered Species Act are especially important to consider when determining whether to take an action under CERCLA Section 104 or 106. Ambient Water Quality Criteria for aquatic organisms are chemical-specific standards that will generally be considered when determining whether to take an action based on the environmental risk of releases to surface waters.

NO-ACTION DECISIONS

If the baseline risk assessment and the comparison of exposure concentrations to chemical-specific standards indicates that there is no unacceptable risk to human health or the environment and that no remedial action is warranted, then the CERCLA Section 121 cleanup standards for selection of a Superfund remedy, including the requirement to meet applicable or relevant and appropriate requirements (ARARs), are not triggered. CERCLA section 121 (a) requires only that those remedial actions that are "determined to be necessary ... under section 104 or ... 106 ... be selected in accordance with section 121." If EPA determines that an action is necessary, the remedial action must attain ARARs, unless a waiver is invoked. Of course, sites that do not warrant action under CERCLA sections 104 or 106 may warrant action under another State or Federal statute, such as RCRA subtitle D requirements for the appropriate closure of a solid waste landfill.

The decision not to take action at an NPL site under section 104 and 106 should also be documented in a ROD. The decision documentation process should include the preparation of a proposed plan for public comment, ROD and eventually a closeout report and Federal Register deletion notice.

POINT OF DEPARTURE WHEN ACTION WARRANTED

Once remedial action has been determined to be warranted, the results of the baseline risk assessment may be used to modify preliminary remediation goals. These preliminary goals are developed at scoping based on ARARs and the 10^{-6} cancer risk point of departure pursuant to NCP section 300.430(e)(2)(i).

USE OF BASELINE RISK ASSESSMENT TO MODIFY PRELIMINARY REMEDIATION GOALS

Remediation goals developed under CERCLA Section 121 are generally medium-specific chemical concentrations that will pose no unacceptable threat to human health and the environment. Preliminary remediation goals are developed early in the RI/FS process based on ARARs and other readily available information.

such as concentrations associated with 10^{-6} cancer risk or a hazard quotient equal to one for noncarcinogens calculated from EPA toxicity information. These preliminary goals may be modified based on results of the baseline risk assessment, which clarifies exposure pathways and may identify situations where cumulative risk of multiple contaminants or multiple exposure pathways at the site indicate the need for more or less stringent cleanup levels than those initially developed as preliminary remediation goals. In addition to being modified based on the baseline risk assessment, preliminary remediation goals and the corresponding cleanup levels may also be modified based on the given waste management strategy selected at the time of remedy selection that is based on the balancing of the nine criteria used for remedy selection (55 Fed.Reg. at 8717 and 8718).

EARLY AND INTERIM ACTIONS

Early operable unit actions (e.g., hot spot removal and treatment) and interim actions (e.g., temporary storage or ground water plume containment) may be taken to respond to an immediate site threat or to take advantage of an opportunity to significantly reduce risk quickly (55 Fed. Reg. at 8705). For example, an interim containment action may be particularly useful early in the process for complicated ground water remedial actions, where concentrations greater than MCLs provide a good indication that remediation of a potential drinking water source is necessary; such quick remedial action is important to prevent further spread of the contaminant plume while a final ground water remedy is being developed.

Early and interim action RODs do not require a completed baseline risk assessment, although enough information must be available to demonstrate the potential for risk and the need to take action. Data sufficient to support the interim action decision can be extracted from the ongoing RI/FS for the site and set out in a focused feasibility study or other appropriate document that includes a short analysis of a limited number of alternatives (55 Fed. Reg. at 8704). These data should include a summary of contaminants of concern, concentrations and relevant exposure information. A discussion should accompany these data explaining the need for immediate remedial action based on the presence of contamination that, if left unaddressed in the short-term, either contributes immediate risk or is likely to contribute to increased site risk or degradation of the environment/natural resources. The early and interim action RODs should note that some exposure pathways at the site may not be addressed by the action.

An interim action ROD eventually must be followed by a subsequent ROD for that operable unit based on the complete RI/FS, that includes the baseline risk assessment, in order to document long-term protection of human health and the environment

at that portion of the site. The interim action ROD, however, should demonstrate qualitatively (and quantitatively if possible) that there is a risk or potential for risk and explain how the temporary measures selected will address a portion of this risk.

DOCUMENTATION OF BASELINE RISK ASSESSMENT RESULTS IN THE ROD

The Summary of Site Risks section of the ROD should include a discussion of the risks associated with current and future land use and a table presenting these risk levels for each exposure medium (e.g., direct contact with soil by potential future residents exposed via incidental soil ingestion and dermal contact). In some situations, risks from exposure via more than one medium (e.g., soil and drinking water) will affect the same potentially exposed individual at the same time. It is appropriate in these situations to combine the risks from the different media to give an indication of total risk that an individual may be exposed to from a site.

In addition to summarizing the baseline risk assessment information, the ROD (except no-action RODs) should include how remedial alternatives will reduce risks by achieving cleanup levels through treatment or by eliminating exposures through engineering controls for each contaminant of concern in each appropriate medium.

The Comparative Analysis should include a discussion of each of the nine criteria; consideration of risk is part of the discussion of several of the criteria. The discussion of overall protection of human health and the environment should include a discussion of how the remedy will eliminate, reduce, or control risks identified in the baseline risk assessment posed through each pathway and whether exposure levels will be reduced to acceptable levels. For example, if direct human contact with contaminated soil is identified as a significant risk at a site, the ROD (except no-action RODs) should indicate how the selected remedy will eliminate or control exposures to ensure protection of human health. The discussion of long-term effectiveness and permanence should include, where appropriate, an assessment of the residual risk from untreated residual waste remaining at the site. The short-term effectiveness discussion should address risks during remedial action to those on-site and nearby.

Finally, that part of the Decision Summary in the ROD that focuses on the selected remedy should show:

- the chemical-specific remediation level and corresponding chemical-specific risk level(s) to be attained at the conclusion of the response action and the points (or area) of compliance for the media being addressed; and

- The lead agency's basis for the remediation levels (e.g., risk calculation, ARARs).

The attached table, "Remediation Levels and Corresponding Risks," provides a direct means of displaying this information for health risks and, where appropriate, environmental protection (Table 1). The table should be completed for all media for which the ROD selects final cleanup levels. The table should serve as a summary of text in the selected remedy section of the ROD Decision Summary. For interim action RODs, only qualitative statements may be possible.

Additional guidance on the baseline risk assessment and its role in remedy selection is available from several sources. For guidance on the baseline risk assessment contact:

David Bennett, Chief
Toxics Integration Branch (OS-230)
Hazardous Site Evaluation Division
Office of Emergency and Remedial Response
phone: (FTS) or (202) 475-9486.

For additional guidance on the interaction of the baseline risk assessment and Superfund remedy selection, contact:

David Cooper
Remedial Operations and Guidance Branch (OS-220W)
Hazardous Site Control Division
Office of Emergency and Remedial Response
phone: (FTS) 398-8361
(commercial phone: (703) 308-8361)

For guidance on enforcement-lead sites contact:

Stephen Ells
Guidance and Evaluation Branch (OS-510)
CERCLA Enforcement Division
Office of Waste Programs Enforcement
phone: (FTS) or (202) 475-9803.

NOTICE: The policies set out in this memorandum are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this memorandum, or to act at variance with the guidance, based on an analysis of specific site circumstances. Remedy selection decisions are made and justified on a case-specific basis. The Agency also reserves the right to change this guidance at any time without public notice.

TABLE 1

Remediation Goals and Corresponding Risks [a]

Final Remediation Levels [b]					Corresponding Risk Levels [c]	
					Chemical-Specific RME Risk [d]	
Medium	Chemical	Remediation Level [e]	Point of Compliance [f]	Basis of Goal	Cancer	Non-Cancer
SOIL	A	2.0 ppm	All facility	HI	N/A	0.5
	B	17.0 ppm	grounds	Risk	1.0×10^{-5}	N/A
	C	5.0 ppm		GW Risk	N/A	N/A
GROUND WATER	B	0.1 ppm	Waste Management Unit Boundary	Risk	1.0×10^{-5}	N/A
	C	4.0 ppm		MCL	1.0×10^{-5}	N/A
	F	7.0 ppm		MCLG	N/A	0.2
	G	15.0 ppm		MCL	6.0×10^{-6}	0.09
SEDIMENT	Q	100.0 ppm	Downstream from point A	Ecological Effects	N/A	N/A

a. Prepare summary sheets for selected remedy.

b. Final Remediation Levels are based on preliminary remediation goals developed in the Feasibility Study (FS) (RI/FS Guidance 4.2.1) as modified through the nine criteria evaluation and engineering design. In the process of achieving remediation levels for each chemical, some chemicals will be reduced to concentrations below their remediation levels.

c. Chemical specific risks correspond to associated remediation levels. Risks do not consider effects of exposures to other chemicals or media. If appropriate, risks may be summed to calculate media specific risks. Short term effectiveness is not considered.

d. Cancer risks are measured as individual incremental lifetime; non-cancer as Hazard Quotients.

e. Bases for values should be explained in the earlier Record Of Decision (ROD) table.

f. Bases for location and method for determining attainment (e.g., maximum value detected over area XYZ) should be explained in the description of the selected remedy.

N/A Not applicable

2312

000169

STANDARD OPERATING PROCEDURE
DOCUMENT NO. RASOP:94-1
REVISION NO. 0

-7312

PERFORMING QA/QC CHECKS ON RISK ASSESSMENT CALCULATIONS

RASOP:94-1

Effective Date: 03/04/94

AUTHORIZED BY: Marc E. Nelson — 2/4/94

Marc E. Nelson, Manager
Environmental Planning

Date

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

Fernald Environmental Restoration Management Corporation
P. O. Box 398704
Cincinnati, Ohio 45239-8704

Fernald Environmental FERMCO Restoration Management Corporation	Title: PERFORMING QA/QC CHECKS ON RISK ASSESSMENT CALCULATIONS	
	DOCUMENT NO: RASOP:94-1 REVISION NO: 0	-7312
	Effective Date: 03/04/94	Page 1 of 10

(For Questions, Contact Joe Prince X 8973)

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(For Questions, Contact Joe Prince X 8973)

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION AND AUTHORITY
Draft	0	New document to perform Quality Assurance (QA)/Quality Control (QC) checks on risk assessment calculations for Remedial Investigation/Feasibility Study (RI/FS) reports at the Fernald Environmental Management Project (FEMP).

1.0 PURPOSE

This procedure provides the means for performing QA/QC checks on risk assessment calculations for Remedial Investigation/Feasibility Study (RI/FS) reports at the FEMP. This procedure will include an independent verification of Chemicals of Concern (COC) determinations, source-term concentrations, exposure pathways, exposure receptors, intake parameters, risk equations, risk calculations, and risk-based preliminary remediation goals.

2.0 SCOPE

This procedure applies to Fernald Environmental Restoration Management Corporation (FERMCO) personnel, or the appropriate designee, performing the QA/QC checks on risk assessment calculations.

3.0 DEFINITIONS

Cancer Slope Factor (SF) - A plausible upper bound estimate of the probability of a carcinogenic response as a result of a lifetime exposure to a chemical or radionuclide.

Carcinogen - A chemical or radionuclide that elicits, as its specific defining adverse effect, the production of cancer in animals or humans.

Chemical of Potential Concern (CPC) - A contaminant that is site-related and may be of concern.

Chemical of Concern (COC) - A chemical that has been qualified and selected for quantitative risk assessment. The data collected about this contaminant should be of sufficient quality for use in a quantitative risk assessment.

Dermal Absorption Factor - The relative amount of a substance penetrating the skin epidermis and entering the biological system; a unitless fraction of an applied dose or a percent absorbed.

Gastrointestinal Absorption Factor (GAF) - The efficiency with which cells of the gastrointestinal tract absorb a chemical constituent; unitless, expressed as a fraction.

Hazard Index (HI) - A summation of hazard quotients (HQs) expressing the hazard of exposure to some chemical in a particular medium.

Hazard Quotient (HQ) - The ratio of the concentration of a chemical of concern to a reference dose that assumes a possible deleterious effect. An HQ of one (1) represents the concentration that has been demonstrated to be unlikely to cause a deleterious effect to the most sensitive receptor during a chronic exposure.

3.0 **DEFINITIONS** (cont.)

Intake Rate - The measure of exposure expressed as the mass of a substance in contact with the exchange boundary per unit body weight per unit time (e.g., mg/kg/day; pCi).

Radionuclide - A chemical atom whose nucleus contains an excess number of particles and which undergoes spontaneous disintegration. The emission of the excess energy from that nucleus is termed ionizing radiation.

Reference Dose (RfD) - An estimate of a daily exposure level for the human population that is likely to be without appreciable risk of deleterious effects during a lifetime.

Risk Assessor - The individual or team of individuals who organize and analyze site data, develop exposure and risk calculations, and prepare an estimate of the human health or environmental risks.

Soil K_ds - A partition coefficient that expresses the ratio of the concentration of chemical constituent in the solid and solution components of a geological formation in a specific location.

Toxicant - A chemical capable of producing a deleterious response in a biological system.

Unit Intake Factor (UIF) - For chemicals, the quantity of a chemical intake divided by body weight and duration of time exposed (mg/kg/day); for radionuclides, UIF equals the level of activity that a receptor is exposed to times the duration of the exposure (pCi x day).

4.0 **RESPONSIBILITIES**

FERMCO's Environmental Planning (EP) Department independently checks CPC determinations, source-term concentration calculations, intake parameters, risk equations, and PRG calculations. A minimum of 10 percent of the constituents will be verified.

5.0 **GENERAL**

- FERMCO's Environmental Planning Department will conduct independent checks of FERMCO and/or subcontractor's risk calculations using the FEMP spreadsheet. In some cases, an alternative method for checking the calculations will be used (e.g., a hand calculator, an alternative spreadsheet, or an alternative subcontractor).

- Independent checks will be made of risk calculations using the risk assessment model developed by the EP Department on risk for selected receptors and chemicals for all exposure pathways.

5.0 **GENERAL** (cont.)

- The model has been developed according to the Risk Assessment Work Plan Addendum with appropriate enhancements based on current policies and guidelines developed specifically for the FEMP. The model will be used to calculate site-wide and operable unit Remedial Investigation (RI) baseline risk assessment values, background risks, and preliminary remediation goals.

- Independent calculations will be conducted for those receptors and COCs considered important for the assessment. Calculations will be conducted for all exposure pathways for selected receptors. Independent calculations will be made for selected organic, inorganic, and radionuclides that are COCs. The COCs contributing to the majority of risk will be preferentially selected for QC calculations. This approach is considered adequate since any errors made in a spreadsheet for one chemical and exposure pathway will typically be repeated for calculations made for other constituents.

- Particular contaminants will be selected based on their importance to the results and conclusions of the risk assessment. They will be further examined based upon their known toxicity to certain target organs and the exposure pathway of concern. The receptors will be chosen based on their sensitivity and relative importance to potential health effects and will be selected so that, in combination, all exposure pathways are independently calculated.

6.0 **PREREQUISITES**

6.1 Subcontractors shall prepare and submit a quality assurance plan for approval by the Environmental Planning Department prior to conducting risk calculations for baseline risk assessments.

7.0 **PROCEDURE**

7.1 CHECKING RISK ASSESSMENT DATABASES

RISK ASSESSOR

1. Check values in Databases 1 through 3 (see Table 1, "Risk Assessment Database Summaries") against values used in the risk assessment sources. For example, after Database 1 is created, the values are compared to their references, which include the Integrated Risk Information System (IRIS), the Health Effects Assessment Summary Tables (HEAST), the Environmental Criteria Assessment Office (ECAO) guidelines, and Toxicological Profiles.

7.1 CHECKING RISK ASSESSMENT DATABASES (cont.)

RISK ASSESSOR

2. Check COC determinations and exposure point concentrations for a minimum of 10 percent of the constituents requiring verification.

   a. If deviations are found, do the following:

      (1) Recheck the value.

      (2) Correct it if necessary.

      (3) Note any discrepancies found in the risk assessment under review.

   OR

   b. If deviations are not found, check is complete.

TABLE 1

RISK ASSESSMENT DATABASE SUMMARIES	
Risk assessment databases include the chemical-specific values required for completing risk calculations for all exposure pathways. These databases serve as inputs to the FEMP risk assessment model. A summary of these databases is provided below.	
DATABASE 1	Consists of Cancer SFs, RfDs, Gastrointestinal Absorption Factors, and Toxicity Equivalent Factors.
DATABASE 2	Consists of Biotic-Transfer Factors.
DATABASE 3	Consists of Dermal Absorption Factors and Soil Kps.
DATABASE 4	Consists of Exposure Point Concentrations.

7.2 PERFORMING INDEPENDENT CALCULATIONS

RISK ASSESSOR

1. Independently calculates and checks intakes, risks, and hazard quotients on the six selected constituents for selected receptors and each pathway using the parameters listed in the risk assessment.

7.2 PERFORMING INDEPENDENT CALCULATIONS (cont.)

RISK ASSESSOR

2. Compare the calculated and reported intakes from the report.

3. Compare calculated and reported cancer risk and hazard quotients from the report.

4. Note any discrepancies that exceed 10 percent between calculated and reported values.

5. Attempt to determine the source of differences by comparing observations among all chemicals and all receptors. Some common problems encountered include incorrect exposure parameters, chemical-specific input parameters, dose-response parameters, or incorrect equation programming. (See Table 2, "Calculation Troubleshooting," for examples.)

   NOTE: Six constituents, two from each toxicity category, is considered adequate since any error made in a spreadsheet for one chemical and exposure pathway will typically be repeated for all calculations throughout the column.

7.3 PREPARING CLOSURE DOCUMENTATION

RISK ASSESSOR

1. Prepare an internal memorandum of the QA assessment identifying the form of analysis conducted and noting any deviations, exceptions, or variances (from step 2.a.3 of Section 7.1).

   NOTE: The memo will report the results of the assessment in a table that presents a comparison of the calculated numbers versus those presented in the risk assessment. Separate assessments involving independent risk assessment calculations will be made for each report where significant revisions were made to the analysis.

2. Attach a review record sheet to written responses.

SENIOR TOXICOLOGIST

3. Reviews the memorandum documenting the quality assurance assessment.

   a. If in agreement, inform Risk Assessor.

TABLE 2

CALCULATION TROUBLESHOOTING	
ERROR	**POSSIBLE PROBLEM**
An error that occurs for only one constituent and one receptor	This may be the result of a transposition error. This error would not necessarily be consistent for both the intake and calculated risks or hazard quotients.
An error that occurs only for one chemical but for more than one receptor	This suggests it is the result of the use of a wrong chemical-specific input variable. This error would be consistent for both the uptake and calculated cancer risks or hazard quotients.
An error that occurs for more than one chemical for more than one receptor	This suggests that either an incorrect factor was consistently applied or the intake equation was incorrectly programmed. This error would be consistent for both the intake and calculated cancer risks or hazard quotients.
An error that is detected in the risk calculations for a particular constituent but not the intake factor	This suggests that a wrong dose-response factor was used. This error would not necessarily occur for other receptors and it would be detected by the intake being correct and the calculated risk value or hazard quotient being incorrect.

7.3 PREPARING CLOSURE DOCUMENTATION (cont.)

SENIOR TOXICOLOGIST

OR

b. If not in agreement, work with Risk Assessor until problems are resolved.

7.3 PREPARING CLOSURE DOCUMENTATION (cont.)

MANAGER, ENVIRONMENTAL PLANNING

4. Submits memos to CRUs for necessary corrective action(s).

8.0 APPLICABLE DOCUMENTS

8.1 DRIVERS

- Hamric, P. J., U.S. Department of Energy, Fernald Field Office, Oct. 1993, Letter to N. C. Kaufman, Subject: Operable Unit 4 Remedial Investigation Report and Baseline Risk Assessment.
- Kaufman, N. C., FERMCO, Nov. 1993, Letter to P. J. Hamric, Subject: Quality Assurance for Risk Assessment Calculations.

8.2 REFERENCES

- U.S. Department of Energy, 1992, "Risk Assessment Work Plan Addendum," DOE, Fernald Field Office, Fernald, OH.
- U.S. Department of Health and Human Services (n.d.), "Toxicological Profiles," Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, Washington, DC.
- U.S. Environmental Protection Agency (n.d.), ECAO Guidance, EPA, Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Cincinnati, OH.
- U.S. Environmental Protection Agency, 1991a, "Health Effects Assessment Summary Tables (HEAST), FY 1991," OERR 9200.6-303(91-1), EPA, Washington, DC.
- U.S. Environmental Protection Agency, 1991b, "Integrated Risk Information System (IRIS)," computer database, EPA, Washington, DC.

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Fernald Environmental
FERMCO
Restoration Management Corporation

INTEROFFICE MEMORANDUM

To:	Distribution	Date:	March 4, 1994
Location:	Various	Reference:	
From:	Marc Nelson	FERMCO #:	M:RP(EP):94-0014
Location:	Fernald, MS 65-2	Client:	DOE DE-AC05-920R21972
Extension:	9470	Subject:	RISK ASSESSMENT PROCEDURE RASOP:94-1 FOR PERFORMING QA/QC CHECKS ON RISK ASSESSMENT CALCULATIONS

c: File Record Storage Copy 106.4.11.6
Risk Assessment File 3.1

Attached is the approved Risk Assessment Procedure RASOP:94-1, "Performing QA/QC Checks on Risk Assessment Calculations," to be immediately implemented as described in the procedure.

MEN:dsm
Attachment